

**EXPLORING THE IMPACT OF PSYCHOLOGICAL
FORMULATION ON WORKING ALLIANCE: A MIXED
METHODS, REPEATED SINGLE CASE INVESTIGATION**

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Thesis Abstract

Background

Psychological formulation is a central process in many contemporary evidence-based psychological therapies. Formulation is also considered a core competency of clinical psychology training and practice and is heavily referenced throughout professional standards and guidelines. Despite the significance of formulation in clinical psychology and within wider mental health professions, there is limited evidence to show that formulation benefits the client or improves outcomes in therapy, including the working alliance and measures of distress. Considering the status of psychological formulation, further research is required to examine whether formulation impacts outcomes in therapy.

Aims

The key aims of this study was to investigate whether (1) formulation impacts on working alliance and (2) there is a relationship between formulation, working alliance and psychosocial outcomes. To address these research questions, the study delivered a CBT intervention, incorporating 'product' and 'process' formulations to adults experiencing low mood.

Method

The study used a repeated single-case A-B, mixed methods design. The design included a non-treatment baseline phase (A), measuring weekly symptoms of low mood and was followed by the intervention phase (B), which consisted of eight weeks of CBT focussing on low mood. The CBT intervention incorporated two 'product' formulations (in session 3 and 7) and 'process' formulations, which were delivered throughout. Participants and the therapist completed weekly measures at the end of each session, which included measures of working alliance, depression and well-being. Change interviews were also undertaken at the end of therapy to triangulate results. Data analysis mainly included visual analysis, simulation modelling analysis and clinical/reliable change.

Results

Seven participants were recruited, with five participants completing the full eight week CBT intervention. The analysis showed a slight relationship between formulation and working alliance, although evidence was not robust enough to confirm whether formulation directly impacts working alliance. The results showed mixed findings in terms of the relationship between formulation, working alliance and psychosocial outcomes measured. Although over half of participants showed an improvement in depression and two improved in wellbeing, it was not possible to attribute these changes specifically to formulation.

Discussion

This study contributes to a dearth in the literature surrounding the impact of formulation on outcomes in CBT. The findings discussed are mixed and although tentative conclusions can be made that formulation, particularly the product formulation may have contributed to elements of the working alliance, it is not possible to state that formulation directly impacted on the working alliance. The study also highlights the complexity of psychotherapeutic research and the challenges of disentangling processes to draw conclusions on what variables contribute to changes in outcomes. The utility of single-case designs enables researchers to study complex therapeutic processes using a scientific methodology, ultimately bridging the gap between research and clinical practice. This study provides a platform for future research into formulation and should further consider some of the limitations discussed, e.g., does the accuracy of process formulations mediate the working alliance, is it possible to separate the working alliance from the process of formulation.

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Statement of Contribution

Journal article and extended paper.

- Project Design: Hannah Daniels, Dr Mark Gresswell, Dr David Dawson and Dr Louise Braham
- Application for Ethical Approval: Hannah Daniels
- Recruiting Participants: Hannah Daniels, Dr Tracey Swaffer and members of the Community Mental Health Teams
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- Scoring Measures: Hannah Daniels
- Conducting Change Interviews: Hayley Rose and Kimberley Webb
- Treatment Fidelity Checks: Hannah Daniels and Dr Mark Gresswell
- Process Formulation Checks: Hannah Daniels and Dr Mark Gresswell
- Data Entry: Hannah Daniels
- Data Analysis: Hannah Daniels, supervised by Dr Mark Gresswell and Dr David Dawson. Consultation with Dr Nima Moghaddam.
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Systematic Literature Review

How do clients experience clinical formulation? A systematic review using a meta-ethnographic synthesis

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Abstract

Objectives

The purpose of this review was to systematically search, critically appraise and synthesise qualitative research exploring client's experiences of receiving a formulation.

Methods

The review was conducted in four stages, including a comprehensive search of the literature, data extraction, quality appraisal of identified articles and meta-ethnographic synthesis. Ten studies met the inclusion criteria for the synthesis.

Results

The meta-ethnographic synthesis identified five third-order themes: Collaboration and development of formulation, impact of realisation, relationship with themselves, therapeutic relationship and looking to the future. Themes appeared closely linked and inter-dependant of each other and shaped client's overall experiences of formulation.

Conclusions

The findings of the synthesis emphasise the importance of the therapeutic relationship during the development of formulation, influencing the impact of realisation, the client's level of perceived accuracy and overall engagement with therapy. Clinical implications highlight the importance for clinicians to consider the findings discussed to adapt and develop clinical practice. Future research is recommended into further investigation of the impact of formulation, using both qualitative and quantitative methods. Additionally, the impact of realisation may also be an interesting and valuable area of future research.

Practitioner points

- There are several factors that influence client's experiences of receiving a formulation; however the therapeutic relationship is central to each of these.
- Formulation may not always have a positive impact for clients and the impact of realisation may result in feelings of distress.

Introduction

Formulation is a frequently used skill practiced by Applied Psychologists (British Psychological Society (BPS), 2008). In clinical psychology, the term 'formulation' was first referenced within professional regulations in 1969 (Crellin, 1998). Now, formulation is a core competency of the profession and is a skill at the centre of training and at all levels of practice (Division of Clinical Psychology (DCP), 2011; Harper & Moss, 2003). It provides a way to consider psychological distress without using diagnostic categorisation that minimises individual experiences (Johnston & Dallos, 2013). Professional bodies recommend that formulation should be integrated into all aspects of clinical practice and is heavily referenced within current professional documents (BPS, 2010; Health Professions Council, 2009).

Definition of Formulation

There are many published definitions of formulation, which may explain some of the difficulties when attempting to measure impact. Variance often depends on the therapeutic modality adopted and therefore alters the focus of the formulation. For example, in Cognitive Behavioural Therapy (CBT), the formulation may focus on the development of cognitions and the emotions, physical sensations and behaviours associated with these. Whereas in Cognitive Analytic Therapy (CAT), formulation is referred to as reformulation and the emphasis is placed on the patterns of client's interactions with themselves and with others.

Within CBT, the definition of formulation is suggested as a foundation for developing an understanding of the client's difficulties (Beck, 1995; Eells, 2007). Formulation involves 'collaborative empiricism', a two-way process between the client and therapist to generate a shared understanding of the client's problems (Beck, 1995). This joint process is not just unique to CBT and is also detailed in the Good Practice Guidelines on the use of Formulation (DCP, 2011). The Division of Clinical Psychology (DCP) (2010) proposes that formulation is the summation and integration of knowledge that is retrieved through the assessment process. Furthermore, formulation draws on psychological theory

and research giving a framework to describe the nature of a client's problem, how it developed and how it is maintained.

Background Literature

Despite the clinical and theoretical interest into formulation, there is a distinct paucity of evidence to support its effectiveness as an intervention (DCP, 2011). Kuyken (2006) drew attention to the complexity of researching the effectiveness of formulation, outlining the differences between 'top-down' and 'bottom-up' forms of evidence. Top-down refers to the evidence of key models and theories that formulations are based on and bottom-up is in relation to the evidence of reliability and validity, the process of developing the formulation, i.e. the usefulness for clients and the impact of formulation on clinical outcomes.

As Thew and Krohnert (2015) discuss, top-down evidence is more established in the literature, proposing strong empirical evidence to support theoretical models and constructs that formulations are based on. For example, Clark and Beck (1999) detail a review of the evidence for Beck's cognitive theory of depression and McManus, Sacadura and Clark (2008) suggest robust evidence for a cognitive model of social anxiety.

There is a distinct lack of bottom up evidence to support the use of formulation. Research into the reliability of formulation has mainly focussed on inter-rater reliability (Flinn, Braham & das Nair, 2015) and less on test-retest reliability (Bieling & Kuyken, 2003). In summary, reviews of the evidence suggests that reliability of formulation is mixed across studies (Bieling & Kuyken, 2003; Flinn et al., 2015). Limitations are highlighted in the variability of studies, for example, the level of competency and qualification of the clinician and the different methods used to measure reliability (Flinn et al., 2015). Bieling and Kuyken (2003) stress that reliability does not necessarily equate to validity, which is a related but also separate area of research.

A review of the impact of formulation on therapeutic alliance and treatment outcomes demonstrates that the evidence is mixed (Stewart, 2014). There is no published evidence to suggest that the process of formulation

improves the therapeutic alliance when measured by clients. Interestingly, studies have shown significant results when therapeutic alliance is rated by the therapist, but this is not supported by client ratings (Chadwick, Williams & Mackenzie, 2003; Piper, Azim, Joyce & McCallum, 1991). An increase in perceived accuracy has been correlated with improved therapeutic alliance, however due to limitations of the study design, no cause and effect link can be established (Crits-Christoph, Barber & Kurcias, 1993). Methodological limitations, such as small sample sizes, means that we cannot conclude that formulation does not improve therapeutic alliance (Stewart, 2014). Further research, potentially considering a mixed-methods approach is required to explore this further.

Although some studies have investigated the impact of formulation on therapy outcomes, there is no established evidence to support the claim that formulation improves them (DCP, 2011). Chadwick et al. (2003) explored the impact of CBT formulation on clients with experiences of psychosis. They found no significant differences self-reported anxiety and depression ratings pre and post sharing the formulation. Additionally, Evans and Parry (1996) and Shine and Westacott (2010) also found that sharing a reformulation letter in CAT had no impact on clinical outcomes, including, working alliance, client identified problems, and perceived helpfulness of therapy.

It is clear that research into the reliability and impact of formulation is sparse and evidence is mixed. As already discussed, the variability of the definition, different therapeutic modalities and the limited control of variables in naturalistic studies all contribute to the challenges when measuring the impact of formulation. Having looked at the literature, undoubtedly formulation requires greater attention in research, in order to have a better understanding of the processes involved and the impact on outcomes and client experiences.

Chase Gray and Grant (2005) emphasise the absence of the client voice throughout the literature and this is additionally supported by the DCP's recommendation to research client and carer experiences of formulation (DCP, 2011). There is increased attention in the National Health Service (NHS) to obtain service-user perspectives. Their first hand experiences of using services

offers a unique insight into what is required to improve practice and develop organisations (National Health Service England, 2015). Considering formulation is a core skill of a Clinical Psychologist and the limited empirical evidence to support the use of it, this further stresses the need to explore the client's experience of the formulation process.

Previous Reviews

Previously published reviews have appraised the evidence on the reliability, validity and impact of formulation (Aston, 2009; Bieling & Kuyken, 2003; Flinn et al., 2015; Mumma, 2011). Aston (2009), Bieling and Kuyken (2003) and Mumma (2011) conducted narrative, none systematic reviews and therefore highlight limitations of transparency and replicability. Flinn et al. (2015) detail a comprehensive systematic review of the literature on the reliability of case formulations and outline conclusions consistent with the evidence discussed in the background literature. A review of the literature exploring client's experiences of receiving a formulation has not yet been undertaken, but is clearly required. This would be useful to gain a new insight into client's experiences and contribute to the paucity of literature within this field.

Aims of Review

This review will aim to answer the following question:

How do clients experience receiving a psychological formulation?

Firstly a systematic search and critical appraisal of the literature will be undertaken. Using a systematic methodology will allow the author to reduce the chance of bias imposed on the searching process and will also decrease the chance of papers being missed. The methodology will be transparent and replicable, improving the overall rigour of the review.

The review question will also be answered by undertaking a meta-synthesis, specifically using a meta-ethnography, outlined by Noblit and Hare

(1988). A meta-ethnography is a comparative textual analysis which aims to synthesise and interpret findings across multiple qualitative studies. This involves a process of examining concepts or themes within and between studies and considers how these can be translated into existing or new concepts that encompass all studies in the meta-synthesis.

It is recognised that there are debates surrounding the approaches taken in interpretative research. Some argue that synthesis of qualitative findings is reductionist and destroys the integrity and richness of participant accounts (Sandelowski, Docherty & Emden, 1997). Opposing these arguments, it is suggested that qualitative researchers are at risk of isolating their studies from clinicians and the development of policy documents (Silverman, 1997). Walsh and Downe (2005) propose that synthesising qualitative studies in a related field allows for nuances, assumptions and varying accounts to be explored and discussed, opening opportunities for new perspectives.

Methods

This review was conducted in four stages, i) systematic and thorough search of the literature, ii) data extraction iii) quality appraisal of identified articles and iv) meta-ethnographic synthesis (Nobilt & Hare, 1988).

Searching

Prior to undertaking a systematic search of the literature, scoping searches were carried out to provide the researcher with a clearer understanding of previous reviews and studies conducted into formulation. Previous reviews were read (Aston, 2009; Bieling & Kuyken, 2003; Flinn et al., 2014; Mumma, 2011) and their limitations were also considered.

Two methods were used to undertake a comprehensive search of the literature. Firstly, four electronic, peer-reviewed databases were systematically searched in June 2016: PsycINFO (1806 – present); MEDLINE (1946 – present); AMED (1985 – present); EMBASE (1980 – present). In addition, two electronic, grey literature databases were also searched: Ethos and Open Grey. It was not possible to search these databases using the systematic search

strategy, therefore they were searched using the key terms for 'formulation'. Grey literature databases were added to broaden the search, including a range of resources to ensure full exploration of the phenomena of formulation (Boland, Cherry & Dickson, 2014). Books were excluded from this review as the aim of the review was to obtain first-person, client perspectives of receiving a formulation and the author did not consider books would capture original, empirical research. Doctoral theses were included in this review as they would be assessed against doctoral standard criteria. A manual search of reference lists of previous reviews of formulation was also undertaken.

Terms

The researcher considered the terms and search strategy that previous reviews had used and utilised these for this current review:

formulation*¹ OR psychological formulation* OR case conceptuali?²ation* OR case formulation* OR clinical formulation*OR reformulation* AND service-user* OR client* OR patient AND experience* OR perception* OR view* OR understanding.

Due to a large number of irrelevant studies from pharmaceutical research being captured in the search, the following NOT term was added: pharm*.

All searches included the limits of human participants, participants aged 18 and over, studies written in the English language and excluded book reviews.

Definition of Terms

In this review the definition of experience is the client's lived process of receiving a formulation. Experience may include both internal and external processes, such as emotional, cognitive or behavioural responses.

¹ The suffix * provides a truncation for the search terms in the databases.

² The suffix ? provides a wild card for the search terms in the databases

The definition of formulation will be taken from the DCP (2010) guidelines, which is the summation and integration of knowledge about the client that is retrieved through the assessment process. The formulation will draw on psychological theory to provide an explanation of the client's problem, how it developed and how it is maintained.

Selection

Figure 1 provides a flow diagram, outlining the process of article selection in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher, Liberati, Tetzlaff & Altman, 2009).

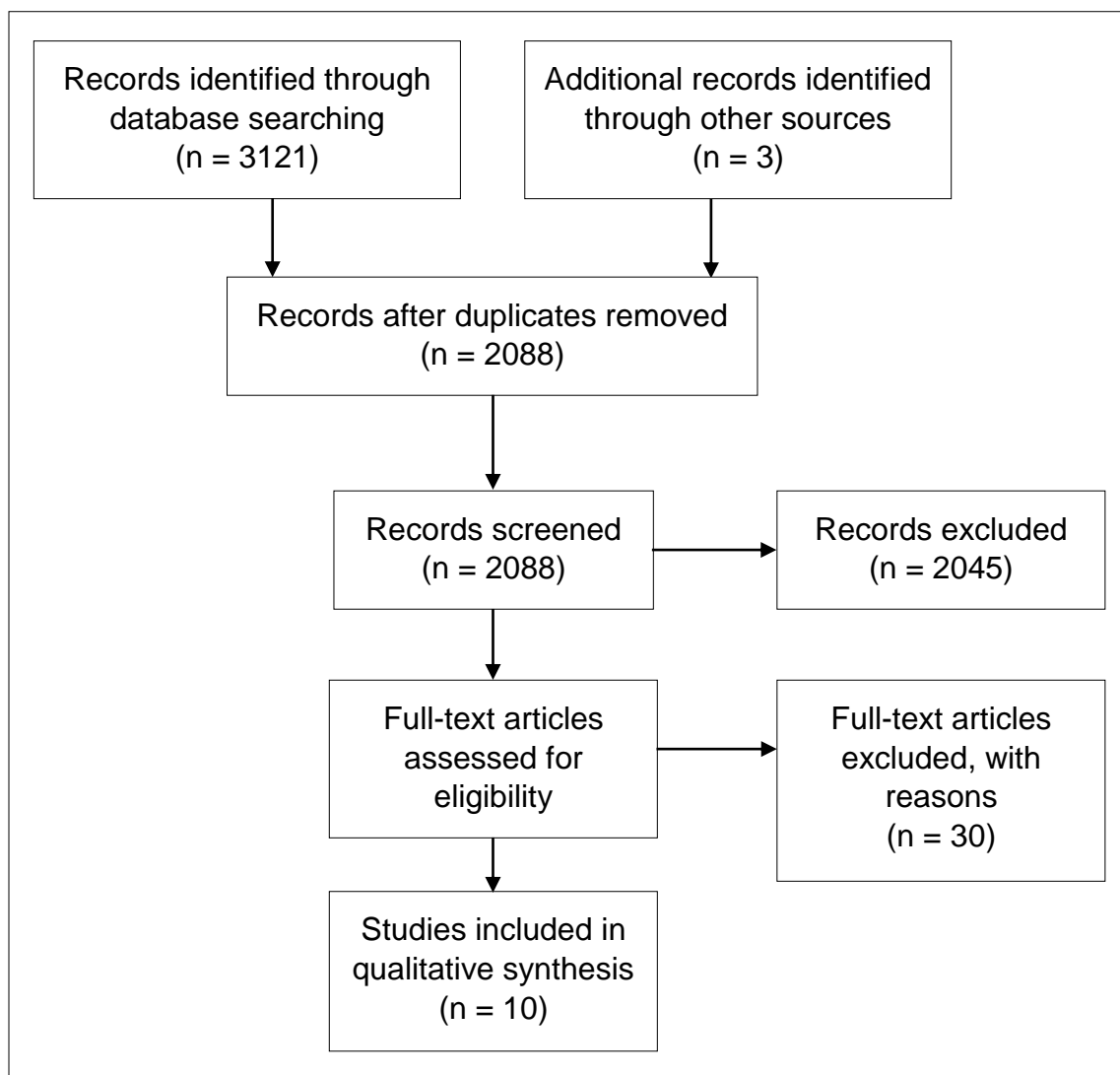


Figure 1. Flow diagram of article selection and exclusion (Moher et al., 2009)

The search strategy retrieved 3114 articles from PsycINFO, MEDLINE, AMED and EMBASE and seven articles from Ethos and Open Grey. Once duplicates had been removed, titles and abstracts were then reviewed applying the following inclusion and exclusion criteria. Three articles were also retrieved from the reference lists of potential identified articles. 40 full-text articles were then reviewed in more detail, also using inclusion and exclusion criteria. Rationale for the inclusion and exclusion criteria were developed through reference to previous reviews on formulation (Aston, 2009; Bieling & Kuyken, 2003; Flinn et al., 2015; Mumma, 2011).

In order to answer the question posed in this review, the following criteria needed to be adhered to.

Inclusion criteria

- Investigated participant's experiences of formulation from a first-person perspective.
- Detailed theoretical model used in the formulation in accordance with the Good Practice Guidelines (DCP, 2011)
- Clearly stated that they were specifically exploring the client's experience of formulation and not other psychological techniques used in the therapy. For example, in CAT, the paper stated they were exploring client's experiences of 'reformulation' and not client's overall experiences of the therapy.
- Qualitative or mixed-methods design
- Used client/service-user participants.
- Participants over 18 years.
- Written in the English language.

Exclusion criteria

- Investigated second person experiences of formulation, e.g. professionals, teams.
- Makes reference to formulation but does not explore client's experiences of formulation.

- Quantitative design.
- Participants under 18 years.

For reference, the researcher recorded reasons for exclusion. 23 articles were excluded as they had not specifically explored client's experiences of formulation and four were excluded as they had focussed on clinician's experiences of formulation. Two articles were excluded, as they had not been explicit in the results whether their data represented participant's experiences of formulation or their experiences of the therapy or other psychological techniques (Kellett & Hardy, 2014; Ryle & Beard, 1993). One article was excluded as the researcher could not differentiate between participant's experiences of the reformulation letters and goodbye letters, and therefore it was not explicit which data explored experiences of the formulation specifically (Hamill, Ried & Reynolds, 2008).

It should also be noted that two unpublished theses were also excluded from the review (Hargate, 2006; Osborne, 2011) as the author was unable to make contact with the author or obtain the thesis from the relevant universities.

Quality appraisal

Quality appraisal is vital for qualitative research, so it can robustly contribute to evidence and inform best clinical practice. The literature provides little consensus as to what the essential criteria are to classify the quality of qualitative research (Ring, Ritchie, Mandava, & Jepson, 2011). This review used the Critical Appraisal Skills Programme (CASP) tool, specifically designed to evaluate qualitative research (Critical Appraisal Skills Programme, 2013). The researcher made an adaption to the CASP tool, by adding one item, which assessed whether the researcher's epistemological position had been considered. In total, 11 quality criteria were applied to each article and were scored either zero if the item was not met, one if it was unclear and two if it was definitely met.

The review used the CASP tool as a means to explore and develop a further understanding of the papers included in the review. It was recognised that whilst some papers may demonstrate higher quality on the CASP tool, all studies may offer valuable findings (Sandelowski et al., 1997).

Data abstraction

There is no agreed preferred method to synthesise qualitative research, however meta-ethnography is the most frequently used and published (Noblit & Hare, 1988). This review followed the seven steps of meta-ethnography outlined by Noblit and Hare (1988). Each article was read, reread and quality appraisal was completed. Data was then systematically abstracted for each article, noting down research aims, methodology, research findings and the authors' interpretation of the data.

A meta-ethnography involves the synthesis of first and second order constructs into a new interpretation, defined as third order constructs (Britten et al., 2002). Malpass et al. (2009) outline a working definition of first, second and third order constructs which has been adapted for this review and is presented in Figure 2. When undertaking a meta-ethnography, accessing first order constructs can be problematic, as the data extracts used in the articles have been abstracted by the authors from the original data set (Atkins et al., 2008). For the purpose of this review, when quotes were provided in the articles, it was considered whether they supported the second order constructs or whether they suggested a new third order construct.

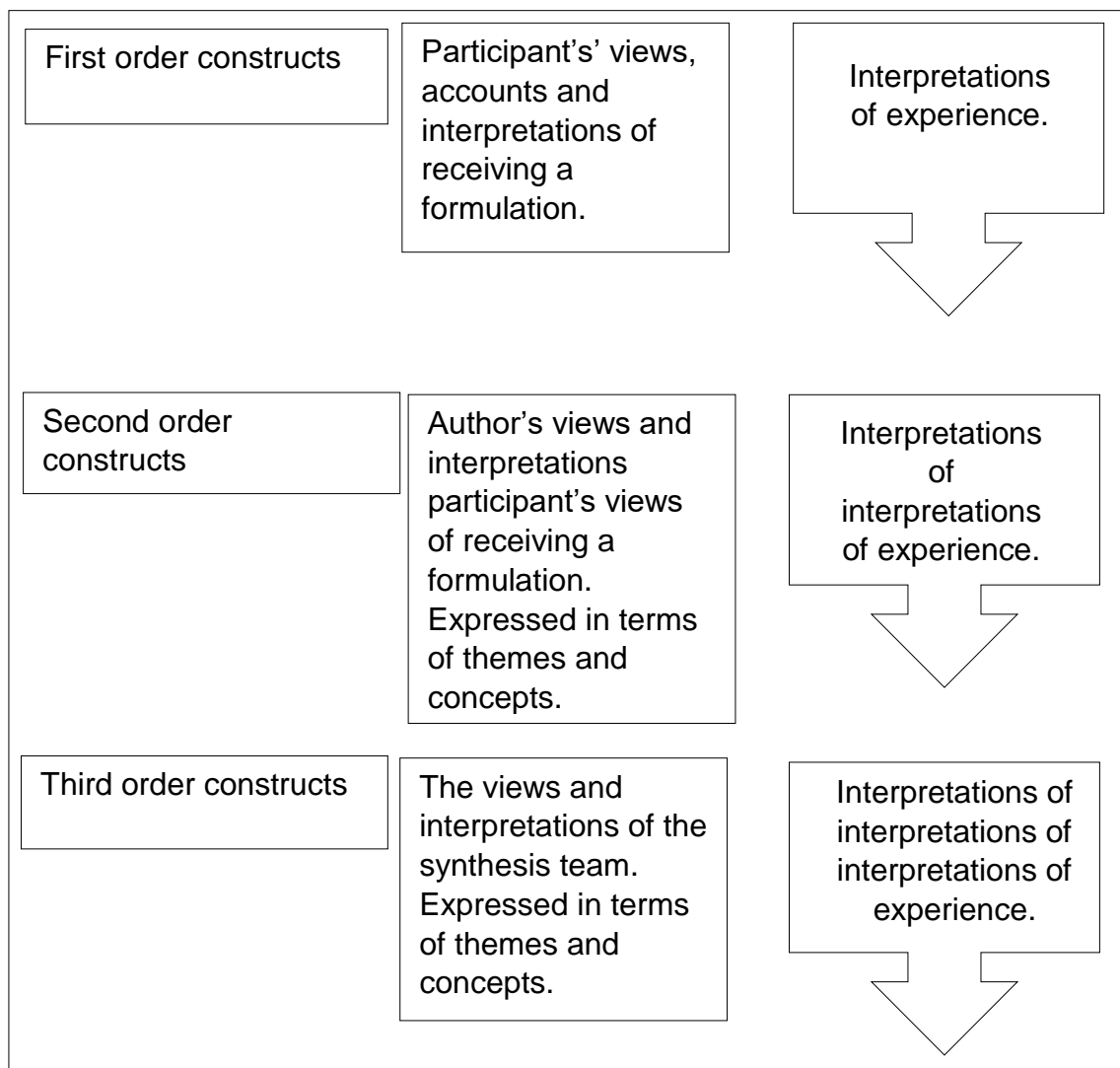


Figure 2. Diagrammatic explanation of first, second and third order constructs.

(Malpass et al., 2009)

A meta-ethnography synthesises and interprets the concepts across the identified studies in three possible ways (Noblit & Hare, 1988), each of which have been employed within this review.

- 1) Reciprocal translation: Identifies similar accounts across studies which can be grouped together or translated into one another. Over-arching concepts are developed using existing concepts from one of the studies or new metaphors that can account for common findings across the papers.

- 2) Refutational synthesis: accounts for conflicting or contradictory concepts between studies identified in the synthesis.
- 3) Line of argument synthesis: develops a new interpretation of the similarities and differences identified across the studies.

Reflexivity

Consideration of the reviewer's reflexivity is important when interpreting qualitative research. Within this review, the author has used an inductive approach to understand client's experiences of formulation. Utilising supervision has enabled the reviewer to develop third order interpretations whilst remaining truthful to participant's original, first-order accounts.

Results

This synthesis interpreted the findings of 10 papers, eight peer-reviewed, published articles and two unpublished doctoral theses. The synthesis included a total of 69 participants and the age of participants was reported in all but one paper (Stewart, 2016), ages ranging from 19 to 78 years of age. Most studies used a qualitative design, three used a mixed-methods design (Chadwick et al., 2003; Evans & Parry, 1996; Shine & Westacott, 2010) and one detailed a case report (Thew & Khronert, 2015). All studies used semi-structured interviews for data collection and papers varied on the chosen method of analysis. Each study referred to the definition of formulation in the introduction, however only one explicitly outlined the definition of formulation used in the study (Redhead, Johnstone & Nightingale, 2015). CAT studies referred to formulation as 'reformulation' and was shared using a reformulation letter or sequential diagrammatic formulation (Rayner, Thompson & Walsh, 2011; Shine & Westacott, 2010). Two studies detailed exactly what information was included in the developmental diagrams and accompanying letters used to share the formulation (Chadwick et al., 2003; Pain, Chadwick & Abba, 2008). The characteristics of studies included in the synthesis are detailed in Table 1.

Table 1.

Characteristics of studies included in the review

Study Number	Authors and year of publication	Journal/Thesis	Methodology	N	Data analysis	Theoretical model used in formulation	Research aims
1	Evans and Parry (1996)	Clinical Psychology and Psychotherapy	Mixed methods	4	Descriptive analysis of key themes	Cognitive Analytic Therapy (CAT)	Investigate the following hypotheses: 1. Clients will perceive the session in which the reformulation was presented as especially helpful. 2. The measure of

							therapeutic alliance would increase following the reformulation.
							3. The measure of magnitude of client's problems would decrease following the reformulation
2	Chadwick, Williams & Mackenzie (2003)	Behaviour Research and Therapy	Mixed methods	11	Descriptive analysis of key themes	Cognitive Behaviour therapy (CBT)	Assess the impact of case formulation in CBT or psychosis. Investigate the following hypotheses:

							1. Formulation
							enhances therapeutic alliance
							2. Formulation eases distress
							Research question:
							How relevant and helpful is case formulation?
3	Brown (2008)	Unpublished thesis	Qualitative	6	Grounded theory	CBT, CAT, Dynamic and Integrative	To explore clients' experience of formulation.
		Submitted for Doctorate in Clinical Psychology at					

		the University of Coventry					
4	Pain, Chadwick & Abba (2008)	British Journal of Clinical Psychology	Qualitative	13	Content analysis	CBT	Explore clients' experience of case formulation in CBT for psychosis.
5	Shine & Westcott (2010)	Psychology and Psychotherapy: Theory, Research and Practice	Mixed methods	5	Template analysis	CAT	To investigate whether the reformulation process in CAT has an impact upon a measure of working alliance and to explore client's perspective on the reformulation process.

6	Rayner, Thompson & Walsh (2011)	Psychology and Psychotherapy: Theory, Research and Practice	Qualitative Semi- structured interviews	9	Grounded theory	CAT	<p>1. To explore and describe the experience of receiving CAT.</p> <p>2. To gain a better understanding of the use of reformulation and specific CAT tools.</p> <p>3. To explore how the use of the reformulation and CAT tools link to clients' understanding of change.</p>
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7	Kahlon, Neal & Patterson (2014)	The Cognitive Behaviour Therapist	Qualitative	7	Thematic analysis	CBT	Explore experiences of CBT formulation in clients with depression.
8	Redhead, Johnstone & Nightingale (2015)	Psychology and Psychotherapy: Theory, Research and Practice	Qualitative	10	Inductive thematic analysis	CBT	Explore clients' experiences of formulation in CBT for depression and/or anxiety.
9	Thew & Khronert (2015)	The Cognitive Behaviour Therapist	Mixed Methods	1	Framework analysis techniques	CBT	Explore the use of formulation as intervention and evaluate ways in which it may or

			Single case report				may not prove helpful.
10	Stewart (2016)	Unpublished thesis Submitted for Doctorate in Clinical Psychology at the University of Sheffield	Qualitative	3	Grounded theory	CBT and Integrative	To develop a model of formulation-sharing based on patients' perspective of the process.

Quality Appraisal

There was some variation in the overall quality of the studies included in the review, with total scores ranging from 14 to 22. It should be noted that both studies deemed the highest quality are doctoral theses and were therefore not restricted by word counts specified by journals. The scoring of each study included in the review are outlined in Table 2.

All but one study included in the synthesis (Thew & Khronert, 2015), clearly outlined the aims of the research and demonstrated the relevance of the study in relation to existing literature on formulation. Although there was some variance in the designs used across the studies, all studies used an appropriate methodology to address the research aims. Half of the studies were not explicit about recruitment methods, which limited the assessment of whether the studies had used appropriate recruitment strategies to address the research aims (Chadwick et al., 2003; Evans & Parry, 1996; Rayner et al., 2011; Shine & Westacott, 2010; Thew & Khronert, 2015).

Despite the influence of subjectivity during the process of interpretation, the relationship between the researcher and participant was acknowledged in only half of the studies (Brown, 2008; Kahlon, Neal & Patterson, 2014; Rayner et al., 2011; Shine & Westacott, 2010; Stewart, 2016). Most studies, with the exception of both doctoral theses (Brown, 2008; Stewart, 2016) failed to consider the epistemological position of the researchers. As a result, this limits the author's ability to fully assess the impact of the researcher's epistemological positions on the design, data collection and interpretation of the findings of all the studies included.

Table 2

Quality criteria scores for studies included in the review

CASP Criteria	Study Number									
	1	2	3	4	5	6	7	8	9	10
Was there a clear statement of the aims of the research?	2	2	2	2	2	2	2	2	0	2
Is a qualitative methodology appropriate?	2	2	2	2	2	2	2	2	2	2
Was the research design appropriate to address the aims of the research?	2	2	2	2	2	2	2	2	2	2
Was the recruitment strategy appropriate to the aims of the research?	1	1	2	2	1	1	2	2	1	2
Was the data collected in a way that addressed the research issue?	2	2	2	2	2	2	2	2	2	2
Has the relationship between researcher and participants been adequately considered?	0	0	2	0	2	2	2	0	1	2
Have ethical issues been taken into consideration?	1	1	2	2	1	2	2	2	1	2

Has the epistemological position of the researcher been considered?	0	0	2	0	0	0	0	0	0	2
Was the data analysis sufficiently rigorous?	0	0	2	2	2	2	2	2	1	2
Is there a clear statement of findings?	2	2	2	2	2	2	2	2	2	2
How valuable is the research?	2	2	2	2	2	2	2	2	2	2
Total score	14	14	22	18	18	19	20	18	14	22

Interpretation of findings

This meta-ethnography identified five third order constructs: (1) Collaboration and development of formulation; (2) Impact of realisation; (3) Relationship with themselves; (4) Therapeutic relationship and (5) Looking to the future. Constructs were explicitly inter-connected, with each theme influencing another. The results will outline each construct in turn, considering both reciprocal and refutational synthesis, before presenting a line of argument. Table 3 presents a cross-comparison of themes across the selected studies.

Collaboration and development of formulation.

Reciprocal translation identified collaboration and development of formulation as a key and recurring theme in all but two papers (Chadwick et al., 2003; Evans & Parry, 1996). The process of how the formulation was developed, i.e. the active participation of both the client and therapist and how the formulation was shared, i.e. diagrammatically or within a letter appeared fundamental in how participants experienced the formulation. Four papers discussed the usefulness of having a tangible tool to help them visualise the links between aspects of their difficulties (Pain et al., 2008; Rayner et al., 2011; Redhead et al., 2015; Shine & Westacott, 2010). Potentially important to their progress and recovery, one participant reflected on the value of having a tool to reference back to; “They’ve been quite useful to bring away with me, to have a look at and use them when I think they might be helpful...I’m not sure I would have remembered everything without them” ³ (Shine & Westacott, 2010, p.171).

Contradictory to this, two papers (Kahlon et al., 2014; Rayner et al., 2011) discussed some participants’ experiences of formulation diagrams as too complex and technical. Feeling confined and restricted by the diagram was a concept explored by Brown (2008), which resulted in feelings of invalidation and impacted on participant’s engagement with the formulation process. One participant described, “It could be an over neat, over tidy way of doing

³ Speech marks indicate direct quotations of participants from original studies.

things...like a scientific formula, cause and effect, whereas maybe things are a bit more irrational than that?” and another participant reflected “It did seem cold and calculated at first...I was insulted a bit, because it is just a piece of paper and you are basically putting your entire being on one piece of paper” (Brown, 2008, p. 71).

Four papers referred to the concept of collaboration between the client and therapist in the development of the formulation (Brown, 2008; Kahlon et al., 2014; Rayner et al., 2011; Stewart, 2016). Developing the formulation in collaboration with the client appeared to be closely linked with the level of perceived accuracy and in turn the participant’s perception of the usefulness of their formulation. The theme of perceived accuracy was discussed by Redhead et al. (2015), highlighting the importance of accuracy in facilitating understanding. For example, one participant explained, “It all just made sense. I got it (the formulation), because it was true. It seemed true to me anyway, it was all what (sic) I felt.” (Redhead et al., 2015, p.459)

Impact of realisation.

The theme impact of realisation was identified through reciprocal and refutational synthesis across all papers included in the study. Two subthemes were created to clearly outline the conflicting accounts at a second-order level: positive emotional response and negative emotional response.

All but one study discussed the positive impact the formulation process had for participants (Evans & Parry, 1996). This positive impact appeared to be in relation to several factors, firstly in relation to participants experiencing a sense of relief. For some, this was a result of receiving an explanation for their difficulties and was pertinent in contributing to feeling understood (Kahlon et al., 2014; Redhead et al., 2015; Shine & Westacott, 2010). This was demonstrated in one participant’s account of hearing her reformulation letter; “...felt like a huge relief and that I was well and truly heard” (Shine & Westacott, 2010, p.169).

In contrast, all studies but one discussed the negative impact of the formulation (Thew & Khronert, 2015). Papers detailed a range of negative emotional reactions experienced by participants in relation to receiving the formulation, including “sadness” (Chadwick et al., 2003; Rayner et al., 2011) ‘over-whelmed’⁴ (Brown, 2008; Evans & Parry, 1996), “doubt” (Brown, 2008) and “worry” (Chadwick et al., 2003). During the process of realisation, an increased awareness of difficulties that have either been unconsciously suppressed or actively avoided by the participant arose to the surface (Brown, 2008; Kahlon et al., 2014; Redhead et al., 2015; Stewart, 2016). One participant described the process as “I think she hit the nail on the head again actually, I think she was just reaffirming something that I perhaps knew deep-down...” (Stewart, 2016, p. 57). Shine and Westacott (2010) identify a theme of ‘feeling exposed’, resulting in feelings of discomfort for participants due to the realisation of their difficulties. Brown (2008) and Rayner et al. (2011) suggest that discomfort should not necessarily be unwelcomed and could be a necessary stepping stone in a participant’s recovery. The impact of realisation appears to change over time and is possibly addressed through the active agent of the therapeutic relationship.

Relationship with themselves.

Six studies clearly discussed a recurrent theme of a change in participant’s relationships with themselves (Kahlon et al., 2014; Pain et al., 2008; Rayner et al., 2011; Redhead et al., 2015; Shine & Westacott, 2010; Stewart, 2016). This appeared to be mainly in relation to an increased understanding of their difficulties. Exploration and recognition of patterns and links within the formulation often appeared to provide participants with an alternative perspective and understanding of their problems (Brown, 2008; Kahlon et al., 2014; Redhead et al., 2015; Shine & Westacott, 2010; Stewart, 2016). One participant demonstrated this stating, “Yeah, it made a bit more sense actually, it seemed to make sense of why I’d been feeling the way I’d

⁴ Inverted commas indicate direct quotes from the authors of original studies.

been feeling and how I could change things and change the way I think about things...” (Kahlon et al., 2014, p. 10).

This enlightenment into their difficulties (Brown, 2008) seemed to be linked to participant’s improved relationships with themselves. Five studies discussed a less judgemental, less critical and more accepting relationship with themselves (Kahlon et al, 2014; Rayner et al., 2011; Redhead et al., 2015; Shine & Westacott, 2010; Stewart, 2016). For example, one participant described their experience of receiving a reformulation letter,

...it made it so much more ordinary. It put me in the position of an observer. It helped me think, well, if this had happened to a stranger and they had coped like this, would I think that they were dreadful? No I wouldn’t...it was a huge relief (Shine & Westacott, 2010, p. 170).

Therapeutic relationship.

Reciprocal translation identified the importance of the therapeutic relationship in all but two studies (Kahlon et al., 2014; Thew & Khronert, 2015). Studies established a symbiotic relationship between the formulation process and the therapeutic relationship. For example, Rayner et al. (2011) discussed the contribution formulation had to ‘cement the therapeutic relationship’. This suggests that the collaborative process during the development of the formulation plays a significant role in the growth of the therapeutic relationship. A participant demonstrated this, reflecting on her reformulation,

The reformulation was proof that she really did know what I felt like. The other doctors listened, but I thought, are they taking it all in, do they care. I couldn’t trust them, but it’s different now. At first I felt the same with my therapist, but since I’ve had the reformulation I’ve had 100% trust in her and don’t hold anything back now (Evans & Parry, 1996, p. 112).

Stewart (2016) proposed that sharing a formulation was like a 'dynamic shift' and participants progressed from being a 'passive recipient of therapy towards being an active agent in the therapeutic process' (Stewart, 2016, p. 57). The importance of establishing a trusting therapeutic relationship at the point of sharing the formulation with participants was also highlighted (Rayner et al., 2011). In some studies where participants had reported feeling sceptical (Brown, 2008) and frightened of the formulation process (Redhead et al., 2015), the therapeutic relationship a vehicle to work through and address participant's anxiety.

Looking to the Future.

Seven studies referenced participant's expectations of their future and how the formulation had impacted upon this (Brown, 2008; Chadwick et al., 2003; Pain et al., 2008; Rayner et al., 2011; Redhead et al., 2015; Stewart, 2016; Thew & Khronert, 2015). A recurring theme of optimism and encouragement for the future was established in seven papers (Brown, 2008; Chadwick et al., 2003; Pain et al., 2008; Rayner et al., 2011; Redhead et al., 2015; Stewart, 2016; Thew & Khronert, 2015). Redhead et al. (2015) identified the theme of a sense of empowerment to move forwards and work through their difficulties. For example, "seeing it all there, it gives you a different perspective...I just felt empowered that I could do something about them (the problems)" (Redhead et al., 2015, p. 462).

Formulation providing a context and rationale for treatment was discussed in two papers (Evans & Parry, 1996; Thew & Khronert, 2015). It seems that the development of the formulation provided participants with a focus for the rest of therapy, which may have not made sense without sharing the formulation.

Table 3

Cross-Comparison of Third-Order Themes

Third order themes and subthemes	Study Number									
	1	2	3	4	5	6	7	8	9	10
Development and use of formulation			*	*	*	*	*	*	*	*
Impact of realisation	*	*	*	*	*	*	*	*	*	*
Positive emotional response		*	*	*	*	*	*	*	*	*
Negative emotional response	*	*	*	*	*	*	*	*		*
Relationship with themselves				*	*	*	*	*		*
Therapeutic relationship	*	*	*	*	*	*		*		*
Looking to the future	*	*	*	*		*		*	*	*

Note. * Indicates if theme is identified in the study.

Line of argument synthesis

A line of argument synthesis involves the creation of an interpretation, drawing together and presenting the findings of the review as a whole (Noblit & Hare, 1988). Synthesis of the 10 studies included in this review present five key constructs, all of which are closely inter-connected with each other. Figure 3 presents a Venn diagram, depicting the interaction between each theme.

The method in which the formulation is developed and shared appears strongly linked with the therapeutic relationship and potentially impacts the process of realisation for the participant. Findings across the studies suggest that developing the formulation in collaboration with the client is key for the quality of the therapeutic relationship and participants overall engagement with the formulation process. The therapeutic relationship appears to be at the core of participant's experiences of formulation. As already discussed, the findings suggest that participants often experience a negative reaction in response to the realisation of their difficulties. The therapeutic relationship is crucial to provide a non-judgemental and containing space to process their responses.

The inter-connection between the therapeutic relationship and the development of the relationship with the self is significant in participant's experiences of formulation. There appears to be a shift during the formulation process, whereby participant's dependence on the therapist reduces as their self-awareness develops. Stewart (2016) also referred to this process, describing participants taking a more active role in therapy.

Participant's expectations for the future and progress in their recovery may be shaped by the development and milieu of the other themes. This highlights the importance of consideration of the issues discussed in the findings when utilising formulation in clinical practice.

Discussion

This meta-ethnography aimed to critically appraise and synthesise qualitative research that explored client's experiences of receiving a formulation. The review identified five inter-connected key themes that shaped overall experiences of formulation.

This review helpfully synthesises the current literature exploring the usefulness of formulation, from a client's perspective. Highlighting and interpreting findings encourages clinicians to develop and adapt their clinical practice to best meet the needs of the client. As previously discussed, the evidence to support the use of formulation is limited, therefore the findings presented in this meta-ethnography are a useful contribution to the literature.

The findings discussed support the DCP's Good Practice Guidelines on the use of formulation (DCP, 2011). It seems reasonable to suggest that the experiences of receiving a formulation are consistent with the main purpose of formulation; to identify the best way forward and to inform future interventions. In addition, the findings also support other aims that a formulation intends to achieve, including, providing an overall picture or map, helping the client to feel understood and contained, strengthening the therapeutic alliance and normalising problems and self-blame. This is a useful finding, confirming that there is consistency between what professional guidelines state are the aims of formulation and what clients perceive they are receiving.

Exploration of the impact of realisation for clients is an interesting finding, particularly the recurrent theme of a negative emotional response from clients. It is important not to take this finding at face value and requires some further consideration. Given that negative findings are often unreported within research papers (Dickersin & Chalmers, 2011), it is reasonable to suggest that feelings of distress are potentially experienced more frequently than is reported within the literature. Negative emotional responses to the formulation, for example, feeling overwhelmed, may indicate a process that is more complex and dynamic, potentially where change has occurred (Stewart, 2016). The interpretations presented in this review also support the idea suggested by Eells (2007) that formulation may reduce client's engagement. This may be as a

result of a conflict between the content of the formulation and a suppressed understanding of their difficulties. Brown (2008) proposes discomfort may be a necessary transition to pass through in order to progress through recovery. Without further exploration of this issue, it is impossible to draw any firm conclusions; however this may highlight an area for future research.

The finding highlighting the importance of the therapeutic relationship during the process of formulation supports existing literature that the therapeutic relationship is key in predicting therapy outcomes (Martin, Garsle & Davis, 2000). The central role of the therapeutic relationship further emphasises the rationale for developing the formulation in collaboration with the client. Supporting previous literature (Crits-Christoph et al., 1992), the review also suggests that the level of perceived accuracy also influenced the therapeutic relationship and the client's overall engagement in therapy.

Limitations

There are several limitations of this review and synthesis. As discussed within existing literature (DCP, 2011), the definition of formulation is open to interpretation and is often dependant on the therapeutic modality used. In addition, the method of sharing or delivery of the formulation may vary amongst clinicians, for example some may use a more formalised, diagrammatic framework and others may deliver a more informal 'micro' formulation, i.e. an interpretation. If authors have not used one of the terms for formulation outlined in the search strategy, they may not have been captured within this review. This does not necessarily mean that these potentially missed papers were not suitable for this meta-ethnography, but highlights the difficulty in the variability of definition when undertaking a literature review.

A strength of this review, is the inclusion of a range of experiences of mental health difficulties amongst participants. Britten et al. (2002) suggest that inclusion of heterogeneous studies can be favourable to obtain richer interpretations in a meta-ethnography. On the other hand, this may also be a limitation as we cannot account for the individual differences amongst participants. For example, participants in Evans and Parry's (1996) study,

described as 'difficult to help', which included two or more episodes with a professional and two or more admissions to hospital, may have very different experiences to those participants included in the Redhead et al. (2015) study. This study included participants from an Improving Access to Psychological Therapies (IAPT) services and excluded significant co-morbidity. Due to the unfeasibility of accessing raw data, it is beyond the scope of this review to conclude how past experiences may have impacted on participant's experiences of receiving a formulation. This could be potentially highlight an area for future research.

This review focussed on the appraisal and synthesis of qualitative research to answer the question; 'how do client's experience receiving a psychological formulation?'. Focussing on qualitative research allowed the reviewer to synthesise the perspectives of participants on their lived experiences of receiving a formulation. Whilst qualitative research allows participants perspectives to be explored in depth, quantitative research allows investigation as to whether an intervention, i.e. formulation, works or not (Boland et al., 2014). Inclusion of quantitative research may have added to this review and allowed further exploration of the impact of formulation.

Future research and recommendations for practice

In conclusion, this review highlights the importance of exploring client's views of formulation in order to further contribute to the evidence. Reviewing the evidence and considering adoptions to practice will enable clinicians to deliver formulations that are most beneficial and attentive to client's needs. Further research investigating the impact of formulation, using both qualitative and quantitative approaches is certainly required. Consideration of the impact of realisation may also provide an interesting and valuable area for future research.

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Journal Paper ⁵

⁵ This journal paper has been prepared for submission to the Journal of Behaviour Research and Therapy. Footnotes are used throughout to signpost the reader to relevant information in the extended paper.

**Exploring the Impact of Psychological Formulation on Working Alliance: A
Mixed Methods, Repeated Single Case Investigation.**

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Abstract

Psychological formulation is a central process in many contemporary evidence-based psychological therapies and is a core competency of clinical psychology training and practice. Currently there is limited evidence to show that formulation benefits the client or improves outcomes in therapy.

This study aimed to investigate whether (1) formulation impacts on working alliance and (2) there is a relationship between formulation, working alliance and psychosocial outcomes.

A repeated single-case A-B design was used, including a non-treatment baseline phase (A) followed by the intervention phase (B); eight weeks of CBT, incorporating formulation, across five participants.

Results showed a slight relationship between formulation and working alliance, although evidence was not robust enough to confirm whether formulation directly impacts working alliance. Results were mixed in terms of the relationship between formulation, working alliance and psychosocial outcomes measured.

Findings discussed are complex and although tentative conclusions can be made it is not possible to state that formulation impacted on outcomes. The study highlights the complexity of psychotherapeutic research and the challenges of disentangling processes in therapy. Findings provide a platform for future research into formulation and should further consider some of limitations discussed.

Keywords: psychological formulation, cognitive-behavioural therapy, working alliance and outcomes

Highlights:

- Investigation of formulation and outcomes in CBT.
- Complex and mixed findings.
- Highlights complexity of psychotherapeutic research.

Introduction

Psychological formulation (often referred to as case formulation, case conceptualisation or clinical formulation) can broadly be understood as a tool, which applies psychological theory to develop a number of hypotheses that offer an explanation of the development and maintenance of a client's difficulties (Butler, 1998; Division of Clinical Psychology (DCP), 2010). The process of formulation should be collaborative and inform the intervention delivered (DCP, 2010). Psychological formulation is considered a core process in many contemporary evidenced-based psychological therapies, for example, in Cognitive Behavioural Therapy (CBT), formulation is described as the foundation for understanding an individual's difficulties, which involves collaborative empiricism between the client and therapist (Beck, 1995; Eells, 2007). As such, formulation is considered a 'core competency' within Clinical Psychology training and practice within the UK and within wider mental health professions (Health and Care Professions Council, 2015; Johnstone, 2018)⁶.

However, despite the centrality of formulation to the profession and the recommendation of professional bodies to use ideographic formulation above structural diagnostic frameworks (Johnstone, 2006), there is limited research to show the benefits of formulation⁷. This includes inconsistent evidence to suggest improved outcomes of distress and the working alliance (Bieling & Kuyken, 2003). There is, however, equivocal evidence that formulation is beneficial to therapy in terms of client's reporting feelings of relief (Redhead, Johnstone, & Nightingale, 2015), optimism and reassurance (Chadwick, Williams, & Mackenzie, 2003). Although, studies have also reported client's negative responses to formulation, such as feeling overwhelmed, frightened (Evans & Parry, 1996) and a sense of realisation, which can reportedly contribute to feelings of sadness and worry (Chadwick et al., 2003). Research has not yet established whether these negative responses are permanent or whether they are latterly followed by a more positive trajectory (Johnstone, 2018). Few studies have examined the impact of formulation on the working alliance. Chadwick et al. (2003) demonstrated that client and therapist experiences of the therapeutic relationship were inconsistent; while some individual participants indicated improved therapeutic alliance, this was not unanimous and was not attributable to the formulation. Furthermore, whilst therapists reported an increase in alliance over the time points in which the formulation was delivered this was not supported by client-reported measures. Similarly, other studies investigating formulation in Cognitive Analytic Therapy

⁶ See extended paper sections 1.1 and 1.2 for further detail on conceptualisation of formulation and a background and content of formulation in clinical psychology.

⁷ See extended paper section 1.3 for further discussion on formulation as an alternative to diagnosis.

(CAT) have found no significant impact on reported levels of working alliance or perceived helpfulness following the formulation (Evans & Parry, 1996; Shine & Westacott, 2010)⁸.

Reasons for such an absence of evidence are perhaps to be found in the nature of formulation itself; the term is difficult to operationalise and can relate to both a process and an outcome, it may look different across therapies and there are issues of quality and reliability. In terms of operationalisation, within the literature, the definition of formulation varies and it is therefore difficult to compare across studies and between therapists. Formulation can be considered as a 'process', via a continuous process of assessment, intervention and discussions when providing an insight into the client's difficulties during a therapy session (British Psychological Society, 2011). In contrast, formulation can be delivered as a 'product', which may be presented diagrammatically or in a written format. With regards to reliability, a recent review of case formulations showed mixed results, with reliability ranging from 'slight to substantial' (Flinn, Braham, & das Nair, 2015). Arguably, low-reliability in formulation is inevitable, as there is not one correct way to formulate (Butler, 2006). Research highlights a lack of agreement over what constitutes a good quality formulation, with minimal guidance or tools available to assess quality (Flitcroft, James, Freeston, & Wood-Mitchell, 2007). Quality can be considered from a top-down or bottom-up approach (Kuyken, Fothergill, Musa, & Chadwick, 2005). A top-down approach would assess the theoretical framework in which the formulation is based on; ensuring the psychological theory used has an evidence-base for the difficulty being formulated and checking whether the clinician is using the psychological theory coherently. A bottom-up approach would assess the quality of the formulation from the client's perspective; considering how helpful the formulation is for the client⁹.

It is difficult to disentangle the process of formulation from factors such as the therapeutic model used and the working alliance. Furthermore, it is possible that formulation might drive some of these processes or there may be a bidirectional relationship between them. Researching such complex processes has become a significant area of interest within psychotherapy studies, contributing to a debate about the role of common and specific factors in therapy. The common factors approach proposes that if all necessary factors are present (see Table 4), any therapy regardless of the therapeutic model, will

⁸ See extended paper section 1.4 for further discussion on existing research on formulation and outcomes.

⁹ See extended paper section 1.5 for discussion on reliability and quality of formulation. See extended paper section 1.6 for discussion on the debate of Evidence Based Practice (EBP) and Practice Based Evidence (PBE).

be efficacious (Wampold, 2001)¹⁰. A recent meta-analysis showed a robust and moderate correlation (.25 - .30) between the alliance and outcomes, across a range of client presentations and therapies (Horvath, Del Re, Flückiger, & Symonds, 2011). Although there is substantial research to support the importance of the working alliance in therapy, the evidence is criticised due to the correlational rather than causal relationship between these two variables (Castonguay, Constantino, & Holtforth, 2006)¹¹.

Table 4

Components of the Common Factors Model (Wampold, 2001)

Common Factors
(a) An emotionally charged bond between the therapist and client. (b) A confiding and healing setting for the therapy to take place. (c) A therapist who provides a psychologically developed and culturally sensitive explanation for the client's emotional distress. (d) An explanation that is adaptive (i.e., provides realistic options for overcoming difficulties) and is accepted by the client. (e) A set of procedures engaged by the client and therapist that leads the client to enact a positive, helpful or adaptive change.

Specifically to CBT, psychological formulation and the working alliance are both deemed to be essential components of the therapy (Beck, Rush, Shaw, & Emery, 1979). Conceptually, it is important to consider the overlap between these processes and question whether it is possible to have one without the other. A factor analysis showed that Bordin’s (1979) definition of working alliance fits CBT well (Andrusyna, Tang, DeRubeis, & Luborsky, 2001). Establishing mutually agreed goals, the tasks involved to achieve the goals, along with the working alliance are all fundamental to CBT (Beck, Rush, Shaw, & Emery, 1979). Considering some of the professional guidelines surrounding psychological formulation (BPS, 2011; DCP, 2010), formulation should be a collaborative process of developing a psychological understanding of the development and maintenance of an individual’s difficulties. One might expect that the process of developing a collaborative formulation, which guides the goals of the intervention should contribute to the client feeling understood by their therapist. If so, it might be assumed that the process of formulation contributes to a bond between the client and therapist, thus fostering an

¹⁰ See extended paper section 1.7 for further detail on the common factors approach.

¹¹ See extended paper section 1.8 for further information on specific factors and Empirically Supported Treatments (EST).

effective working alliance. Although there is an assumed linear relationship between psychological formulation and working alliance (BPS, 2011), this is unsupported by empirical evidence (Bieling & Kuyken, 2003) and does not consider other potential issues, such as the formulation quality, method of delivery and the client's perceived accuracy of the formulation they receive. Given that some of the literature suggests that clients may experience mixed emotional responses, including feeling frightened and overwhelmed following receiving a psychological formulation (Chadwick et al., 2003; Evans & Parry, 1996), it is important to consider the point in which a formulation is delivered. It could be that establishing a positive working alliance prior to sharing a formulation is essential, so that any negative emotional responses can be worked through therapeutically during the course of therapy¹².

It is clear that given the status of psychological formulation in the profession, more research is required to examine whether formulation impacts outcomes in therapy and to disentangle whether formulation drives outcomes or other non-specific processes. Specifically, we wanted to examine whether formulation impacts the working alliance and other secondary outcomes in eight sessions of CBT, primarily targeting low mood. Given Beck et al. (1979) utilises a specific diagrammatic formulation framework, these were referred to as 'product formulations' and delivered twice during therapy. Additionally, more subtle 'process' formulations were also delivered throughout therapy. These were informed by cognitive-behavioural theory and consisted of three key components Antecedent (A), Belief/Cognition (B) and Consequence (C)¹³.

Research Aims and Questions¹⁴

Specifically, the research aimed to examine whether: (1) formulation impacts on working alliance; (2) there is a relationship between formulation, working alliance and psychosocial outcomes. To answer these research questions, the study delivered a CBT intervention, incorporating 'product' and 'process' formulations, to adults experiencing low mood.

¹² See extended paper for section 1.9 and 1.10 on the development of the concept of alliance and an overview of working alliance and outcomes

¹³ See extended paper section 1.12 for detail on the clinical relevance of the study.

¹⁴ See extended paper section 1.13 for further detail on definition of impact.

Method¹⁵

Design¹⁶

This study utilised a mixed methods, repeated single-case (inter-case replication), AB design (Barlow, Nock, & Hersen, 2009). Single Case Design (SCD) studies, which track outcome variables across baseline and intervention phases, are well suited to investigating the relationships between variables at a micro level (Borckardt et al., 2008). In this case, the design of this study facilitates the examination of formulation (as a product and a process), in a naturalistic setting, which is therefore generalisable to clinical practice.

Participants¹⁷

Participants were invited to take part in the study if they met the following inclusion criteria: (a) currently accessing a Community Mental Health Team (CMHT); (b) between the age of 18 and 65; (c) presented with symptoms of depression or experiencing low mood; (d) able to give informed consent; and (e) able to speak and understand English. Participants were not considered for the study if members of their care team considered their risk of harm to themselves or others as too high, e.g. intention to act on a suicide plan.

Four females and one male from adult UK CMHTs participated (age range; 35 - 61, mean age; 44.8). Two additional participants disengaged from the study after one session; one due to a deterioration in her mental health and consequently losing capacity to consent and the other due to choosing to access a different psychological service.

While the primary diagnosis of clients differed, their reason for accessing therapy was to address their experiences of low mood. All participants were prescribed and taking medication to treat their mental health difficulties, two participants had previously received CBT and one had previously received counselling. See Table 5 for participant's demographics.

¹⁵ See extended paper section 2.1 for discussion on epistemology of the study.

¹⁶ See extended paper section 2.2 for extended rationale for study design and critique of SCD approach.

¹⁷ See extended paper sections 2.3 for detail on justification for sample size and section 2.4 for further information about the participants.

Table 5

Participant demographics

Participant Number	Pseudonym	Gender	Ethnicity	Diagnosis	Previous Psychological Treatment	Type of Medication
1	Luke	Male	White European	FEP	None	Antipsychotic Antidepressant
2	Louise	Female	White British	BPD	CBT	Antidepressant
3	Julie	Female	White British	Bipolar Disorder	None	Mood Stabiliser Antidepressant
4	Heather	Female	White British	Paranoid Schizophrenia	CBT	Antipsychotic Antidepressant
5	Amy	Female	White British	BPD	Counselling	Antidepressant

Note. FEP = First Episode Psychosis. BPD = Borderline Personality Disorder. CBT = Cognitive Behavioural Therapy.

Measures¹⁸

A combination of established measures and purpose-built recording sheets (to count the frequency of process formulations delivered) were utilised in the study. (See Appendix A – D for copy of measures; Appendix E for process formulation recording sheet).

During the baseline phase, the Patient-Reported Outcomes Measurement Information System (PROMIS) depression – short form measure (Cella et al., 2010) was administered at three data points prior to the intervention phase to assess for stability, against which intervention could be compared. The PROMIS depression measure was then administered weekly throughout the intervention.

In addition to a measure of low mood, measures relating to working alliance (Working Alliance Inventory-Short Form; WAI-SF) and wellbeing (Mental Health Continuum-Short Form; MHC-SF) were administered weekly (following each therapy session delivered; see Table 6 below). Finally, the Clinical Outcomes in Research Evaluation – Outcome Measure (CORE-OM) (Evans, Mellor-Clark & Mar, 2000), used as a standard outcome measure at the recruitment sites was administered pre and post intervention.

Formulations¹⁹

Given the research aims, the researchers needed to measure process and product formulations throughout the intervention. Therefore, we defined and measured these in the following ways;

i) Process formulation

Process formulations were coded as verbal summaries or insights that aimed to assist the client's understanding of their difficulties. These were delivered at any point throughout the intervention when the therapist utilised their clinical judgement and felt it was an appropriate instant to share the formulation. In order to be coded as a process formulation, these summaries had to explicitly specify a three terms contingency; antecedent (A), belief/cognition (B) and consequence (C), which may have consisted of parts of the larger (product) formulation. For example, Therapist: "I wonder whether after you have seen your children (A), you feel sad and feel no

¹⁸ See extended paper section 2.6 for extended information about the measures used (2.61 on WAI-SF, 2.62 on PROMIS Depression Measure, 2.63 on MHC-SF, 2.64 on CORE-OM)

¹⁹ See extended paper section 2.7 for further detail on rationale for delivering process and product formulations.

motivation to do anything (C), because you think you have let them down and you are not a good father (B),

ii) Product formulation

A product formulation was delivered in a diagrammatic form, using the Beck longitudinal model (Beck, 1995) and was drawn out on large pieces of paper collaboratively during the session. The product formulation was delivered twice during the intervention phase; in session 3 and 7. (See Appendix F for Beck longitudinal model)

Change Interviews

Interviews were informed by Elliott's change interview (Elliott, Slatick, & Urman, 2001) and were undertaken by an independent researcher (interview schedule in Appendix G). They aimed to explore participant's experience of change, if any, during and after the intervention, asking whether changes were as a result of the formulation or any other factors, related and external to therapy. Participants were also asked specifically about their experiences of developing and receiving a formulation. The qualitative data aimed to triangulate with the quantitative data and to gain participant's accounts of receiving a formulation.

Procedure²⁰

Ethics²¹.

This study was approved by a Research Ethics Committee (REC) and the Health Research Authority (HRA) within the NHS. Also, the study was approved by the University of Lincoln, School of Psychology Research Ethics Committee (SOPREC). (See Appendices H – M for ethical approval letters) In summary, all participants gave informed consent, were aware that therapy sessions were audio recorded and understood that their participation in the study was entirely voluntary. (See Appendix N for consent form, O for information sheet and P for debrief sheet)

²⁰ See extended paper section 2.8 for further information on procedure.

²¹ Section extended paper section 2.8.1 for additional information about ethical considerations and approval.

Recruitment.²²

Participants were recruited from two adult CMHTs. First contact was with their known clinician and if they met the inclusion/exclusion criteria, an information sheet and consent form was sent out. The researcher contacted them after one week to obtain verbal and written consent.

Baseline²³.

Once consent was obtained, participants commenced the baseline phase, which consisted of weekly completion of the PROMIS depression measure, for three data points (Kratochwill et al., 2010). Participants were given the option of completing the baseline measure online (Qualtrics) or in paper format. While establishing a stable baseline is the gold standard in single-case research, due to using a clinical sample, this was not ethically possible in this study.

Intervention²⁴.

Participants received eight, one-hour sessions of CBT weekly. See Figure 3 for illustration of the procedure and structure of the intervention. The lead researcher was the therapist for the intervention and received 90 minutes of clinical supervision weekly, and also kept reflective supervision notes²⁵. The Cognitive Therapy Rating Scale (CTRS) (Young & Beck, 1980) was used to rate CBT adherence. The CTRS was scored for every session by the therapist and one full session, for each participant was second-rated by the supervisor (David, Szentagotai, Lupu, & Cosman, 2008; Westra, Arkowitz, & Dozois, 2009)²⁶. All sessions were audio recorded so the frequency of process formulations could be counted using the process formulation criteria outlined previously²⁷. (See Appendix Q for CTRS)

The intervention delivered was CBT for low mood, informed by Beck (Beck et al., 1979), which aimed to improve the participant's mood, by targeting their cognitions and behaviour.

²² See extended paper section 2.9 for further discussion on recruitment challenges.

²³ See extended paper section 2.10 for further detail on the baseline phase, stability and number of data points.

²⁴ See extended paper section 2.11 for additional information on the CBT intervention.

²⁵ See extended paper section 2.12 for further details on managing the dual role as researcher and therapist.

²⁶ See extended paper section 2.5.5 for additional information on CTRS.

²⁷ See extended paper section 2.13 for extended detail on second coding of process formulations.

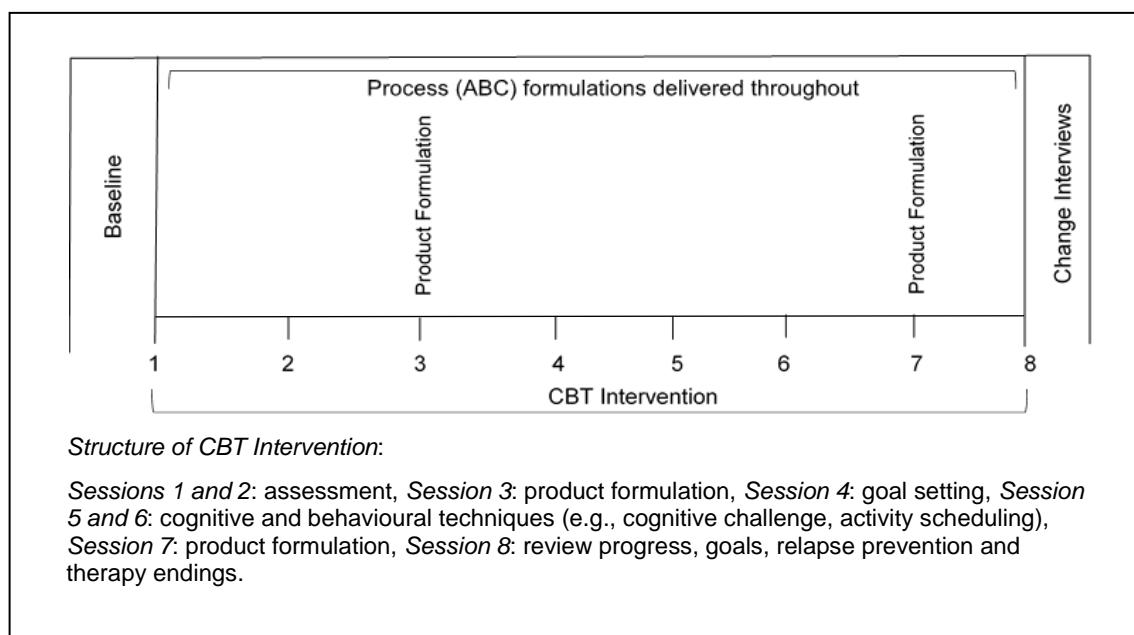


Figure 3. Overview of Single Case Design used in the study.

Table 6

Weekly measures: Characteristics and Psychometric Properties

Measure	Aim	No. of items and scaling	Example item	Directionality and Scoring	Reliability (IC and TR)	Validity
WAI-SF; Client Version Tracey & Kokotovic (1989)	Measures working alliance; consists of three subscales; task, goal and bond.	12 items (3 subscales) 7-point Likert scale (1-7)	(Researcher's name) and I are working towards mutually agreed upon goals.	Higher scores indicate a stronger working alliance. Range: 12-84	IC $\alpha = .86-.82$ (task); $\alpha = .73-.82$ (goal); $\alpha = .80-.83$ (bond) $\alpha = .91-.92$ (total) (Busseri & Tyler, 2003)	Good convergent validity with related measures (Hatcher & Gillaspy, 2006)

WAI-SF; Therapist Version Tracey & Kokotovic (1989)	Measures working alliance; consists of three subscales; task, goal and bond.	12 items (3 subscales) 7-point Likert scale (1-7)	I believe (client's name) likes me.	Higher scores indicate a stronger working alliance. Range: 12-84	IC $\alpha = .86-.90$ (task); $\alpha = .81-.90$ (goal); $\alpha = .77-.86$ (bond); $\alpha = .91-.96$ (total) (Busseri & Tyler, 2003)	Good convergent validity with related measures (Hatcher & Gillaspy, 2006)
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PROMIS Depression – Short Form (8b) Measure (Cella et al., 2010)	Measures affective and cognitive aspects of depression.	8 items 5-point Likert scale (1-5)	In the past 7 days...I felt worthless.	Scores transformed into T-scores. Higher scores indicate higher levels of depression.	IC $\alpha = .90$ (Vilagut et al., 2015).	Good convergent validity with related emotions. Able to discriminate between depression and other co- morbidities. (Vilagut et al., 2015).
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MHC-SF (Keyes, 2002)	Measures wellbeing; consists of three dimensions; emotional, psychological and social wellbeing.	14 items (3 subscales) 6-point Likert scale (0-5)	During the past week, how often did you feel...satisfied .	Scores calculated as averages. Higher scores indicate an improved wellbeing. Range: 0-5Scoring categories: <i>"languishing"</i> (Score of 0-1 on at least one emotional and six other items) <i>"flourishing"</i> (Score of 4-5 on at least one emotional and six other items) <i>"moderately mentally healthy"</i> (any other combination)	IC $\alpha = .92$ (Keyes et al., 2012) TR $r = .68$ (Lamers et al., 2011)	Good convergent validity, subscales correlate with related measures. Good discriminant validity with two-contina model of mental health.
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CORE-OM (Evans et al., 2000)	Measures therapeutic outcomes across four dimensions (functioning, problems/symptoms, wellbeing and risk)	34 items (4 subscales) 6-point Likert scale (0-5)	Over the last week, I have thought of hurting myself.	Scores calculated as averages multiplied by 10. Higher scores indicate higher levels of mental health difficulties.	IC $\alpha = .91$ (Connell et al., 2007) TR $r = .91$ (Connell et al., 2007)	Good convergent validity, subscales highly correlated with related measures.
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Range: 0-10

Note: WAI-SF = Working Alliance Inventory – Short Form; MHC-SF = Mental Health Continuum – Short Form; PROMIS = Patient Reported Outcomes Measurement Information System; CORE-OM = Clinical Outcomes in Research Evaluation – Outcome Measurement; IC = Internal Consistency; TR = Test-Retest

Analysis²⁸

Visual analysis was used to examine trend, variability and points of interest in the data. Visual analysis remains the gold standard by which single-case designs are most commonly analysed, however some argue that statistical methods should also be used alongside (Smith, 2012). To strengthen the visual analysis, Simulation Modelling Analysis (SMA; Borckardt et al., 2008) was undertaken to examine the relationships across variables. SMA is a bootstrapping method used to analyse auto correlated data, to reduce the risk of making Type-I errors. That is, SMA helps determine how likely it is that we would find a correlation between variables when there is none, by examining non concurrent relationships (Nash, Borckardt, Abbasa, & Gray, 2011). In this study, SMA examined temporal relationships between two variables over the course of the intervention, e.g., do changes in the frequency of process formulations precede changes in participant ratings of alliance? A minimum number of three replications, across participants was required to confirm any measured change reflects a relationship between variables (Kratochwill et al., 2010)

In order to more accurately determine whether formulation and working alliance impacted on depression, a baseline assessment of depression was initially undertaken to determine the level and trend of this variable prior to intervention. This was undertaken with the rationale that determining the overall trend of this variable would allow for a clearer assessment of the co-variation between variables (depression, working alliance and formulation) to be made. In order to determine whether any changes in secondary outcome measures were deemed reliable (beyond what could be accounted for due to measurement error at 95% confidence) and clinically significant (placing the participant in a non-clinical range. Jacobson and Truax's (1991) Reliable Change Index (RCI) and Clinical Significant Change (CSC) scores were also calculated.

Participant's responses from the change interviews were tabulated and considered alongside the quantitative data. This method of triangulation enabled the researcher to strengthen or contest inferences made regarding the effect of formulation on the working alliance and secondary outcomes.

²⁸ See extended paper section 2.14 for extended analysis.

Results

Treatment Fidelity

In order to assess treatment fidelity, the CTRS was completed by the therapist whilst listening back to audio recordings for each session. To assess inter-rater reliability, an independent rater (supervisor) listened to the audio recordings of one full session, for each participant (12% of sessions delivered) and sessions were chosen randomly using an online number generator. The independent rater scored the CTRS and recorded the frequency of process formulations ($\alpha = .88$). On the CTRS ratings differed slightly (+ or - 1 point difference on some items) and therapist ratings tended to be lower than the independent rater. Product formulations were also discussed and checked prior to sharing with participants.

This study firstly examined whether:

(1) Formulation impacts on working alliance.

To examine the trend and variability of the WAI and formulations (process and product), visual analysis was undertaken. Particular attention was given to points of interest in the data, i.e. the two data points where the product formulation was delivered. Graphical displays of the data are provided in Figure 4. P2's second product formulation was delayed (delivered in session 8) and as a result the intervention was 9 sessions long. This was due to particularly distressing content shared by the participant during session 7.

The data showed an upward trend on both participant and therapist measures of working alliance for all but one participant (P3). P3 showed a flat trend on the participant working alliance measure. There is little variability on the measures of working alliance across participants and the therapist's measure of alliance is lower than all participant's. However, P2 is the only participant where the therapist's measure of working alliance is higher than the participant's at the end of the intervention. There was moderate variability in the frequency of process formulations delivered across participants, with the lowest total of formulations delivered with P3 (total = 21) and the highest total delivered with P1 (total = 45)²⁹. Visual inspection of the graphs showed that there is a slight peak in the measure of working alliance reported by the therapist for P1, P2 and P4, at the point the second product formulation was delivered. Participant's report of working alliance showed a slight elevation at the first product formulation for P3 and P5 and at the second product formulation for P4. The peak in working alliance, at these points of interest in the data is very slight and is not the only point of elevation during the intervention.

²⁹ See extended paper section 3.4 for means, standard deviations and totals for all measures and process formulations for each participant.

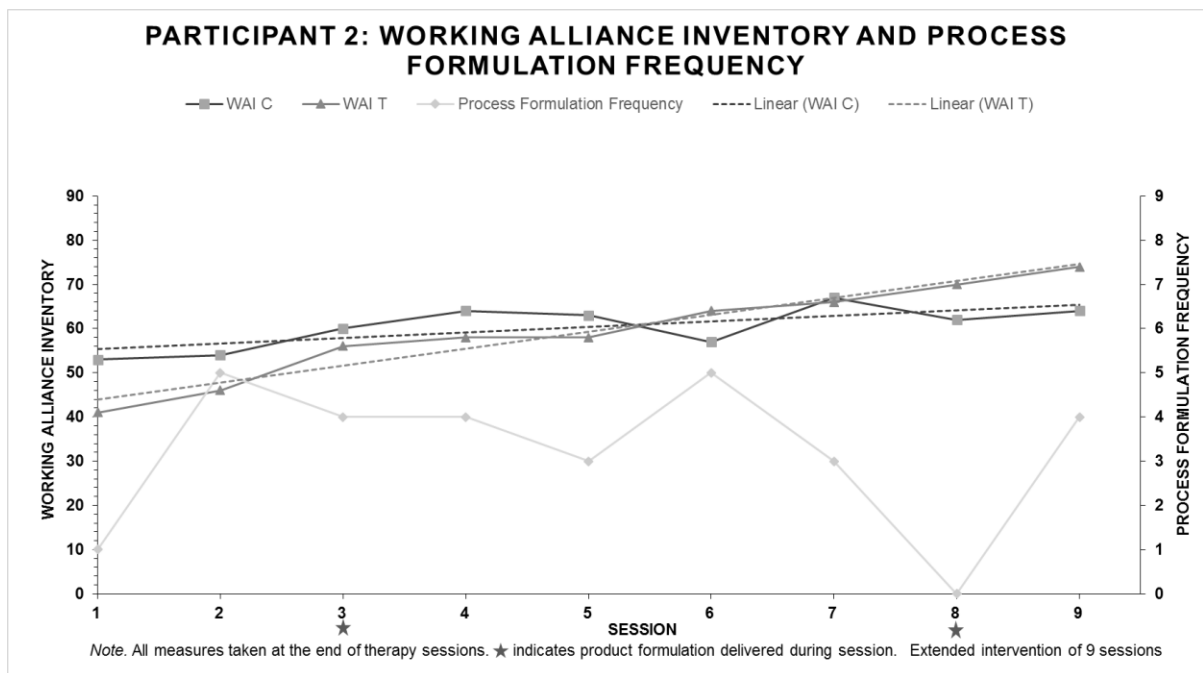
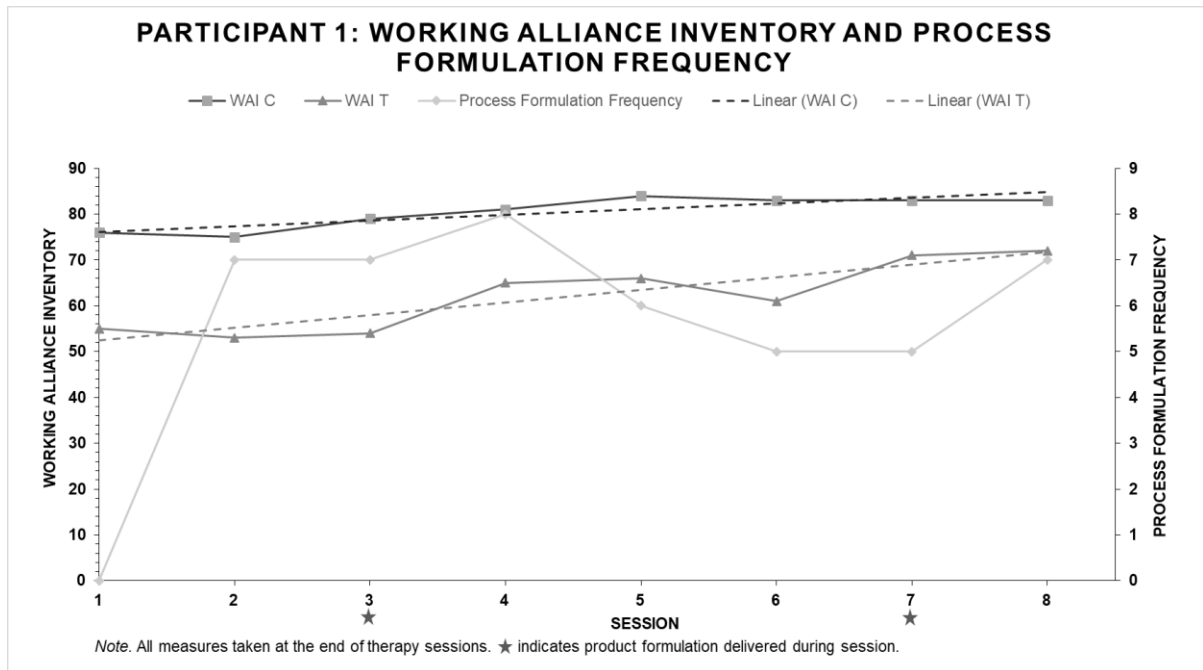


Figure 4. Graphs representing Working Alliance Inventory and process formulation frequency

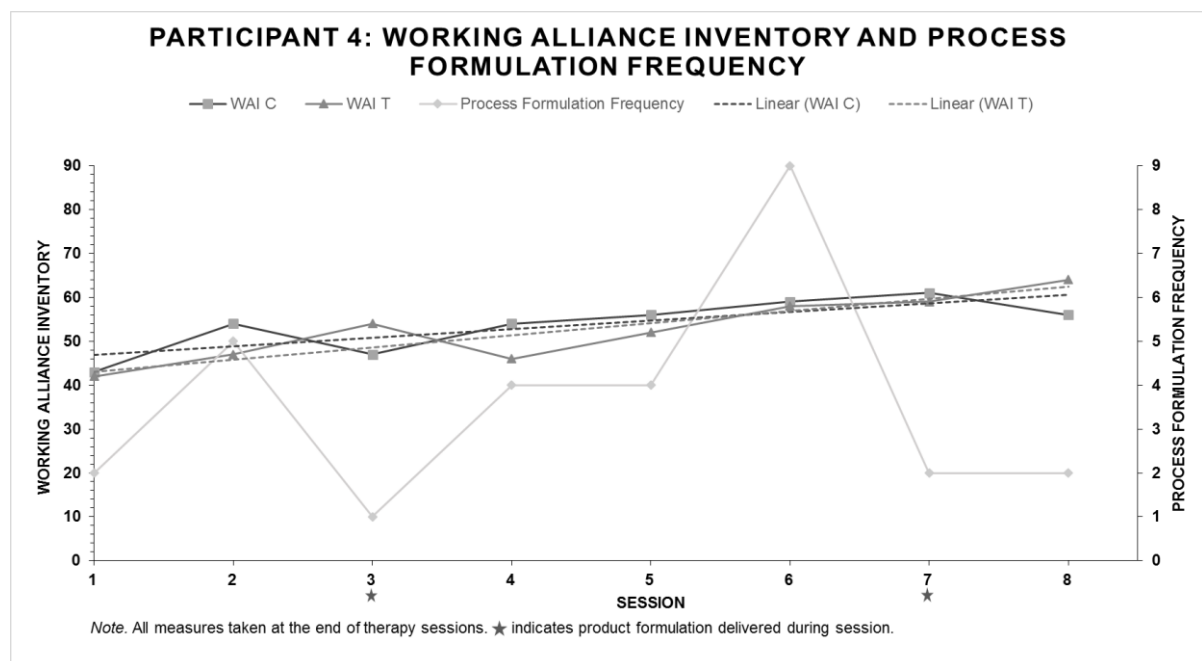
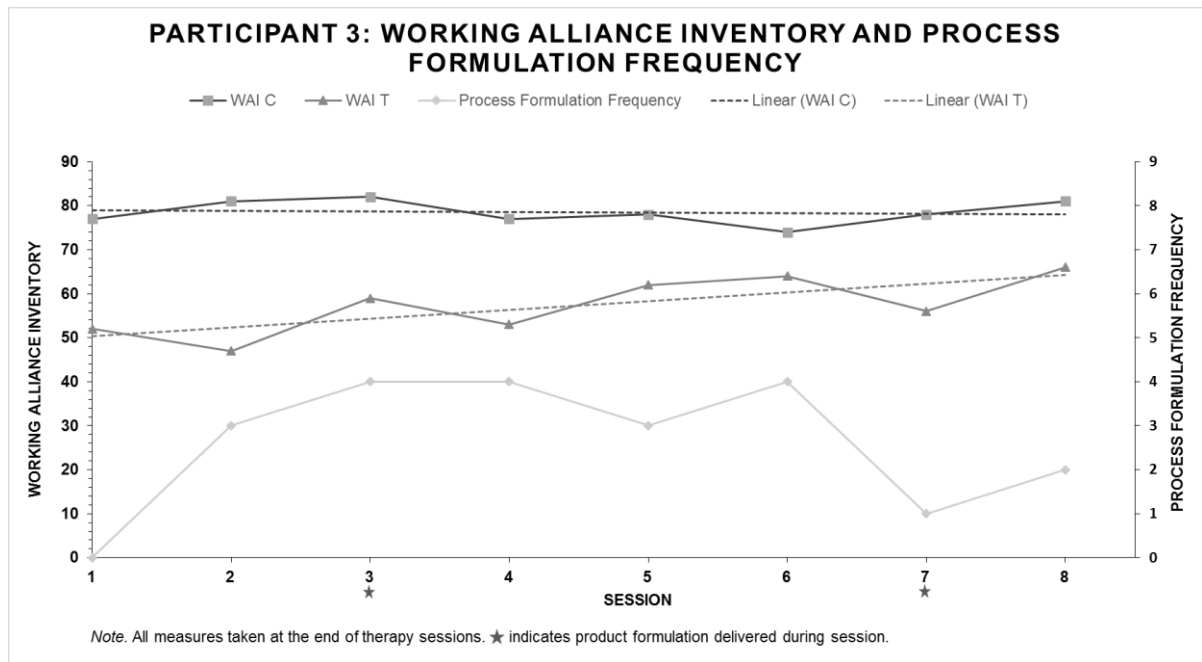


Figure 4 continued. Graphs representing Working Alliance Inventory and process formulation frequency

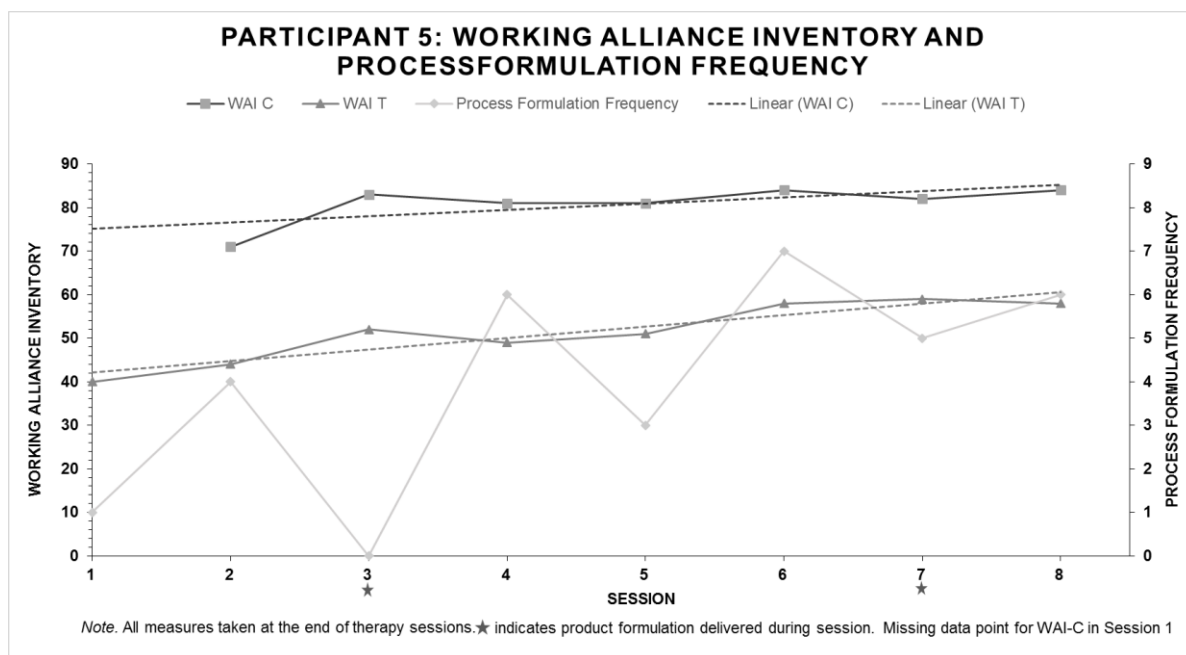


Figure 4 continued. Graphs representing Working Alliance Inventory and process formulation frequency

SMA was undertaken to analyse the relationship, including any lagged relationship between the frequency of process formulations and the working alliance. The analysis showed very few significant correlations between working alliance and the frequency of process formulations. Two participants (P3, $r = +.77$; P5, $r = +.79$) showed that an improvement in participant reported working alliance preceded an increased frequency of process formulations delivered by the therapist in the following session. However this does not meet replication criteria (minimum number of 3). No statistically significant correlations were found between process formulations and therapist reported working alliance³⁰.

In summary, visual analysis and SMA suggests a slight trend between working alliance and formulation. Specifically, visual analysis showed a trend between therapist reported working alliance and the product formulation and SMA suggested a trend between a higher frequency of process formulations and improved working alliance rated by the participant.

Secondly, this study examined whether:

(2) There is a relationship between formulation, working alliance and psychosocial outcomes.

To examine trend and variability of the PROMIS depression measure, visual analysis was undertaken. Changes from baseline to intervention were examined in order to more accurately analyse the trend and variability of depression prior to introducing the intervention. Graphical displays of the data are provided in Figure 5. Most participants showed an improving trend in depression during the baseline phase (P1, P2 and P4), one participant showed a relatively stable baseline (P5) and one showed a worsening trend prior to commencing the intervention (P3). There was little variability in participant's depression scores throughout the intervention, with P2 showing most variation. Focussing on points of interest in the data, one participant (P1) showed highest scores of depression during sessions of highest frequency of process formulations, although this was not repeated with other participants.

³⁰ See extended paper section 3.5 for SMA correlation coefficients for frequency of process formulations and working alliance.

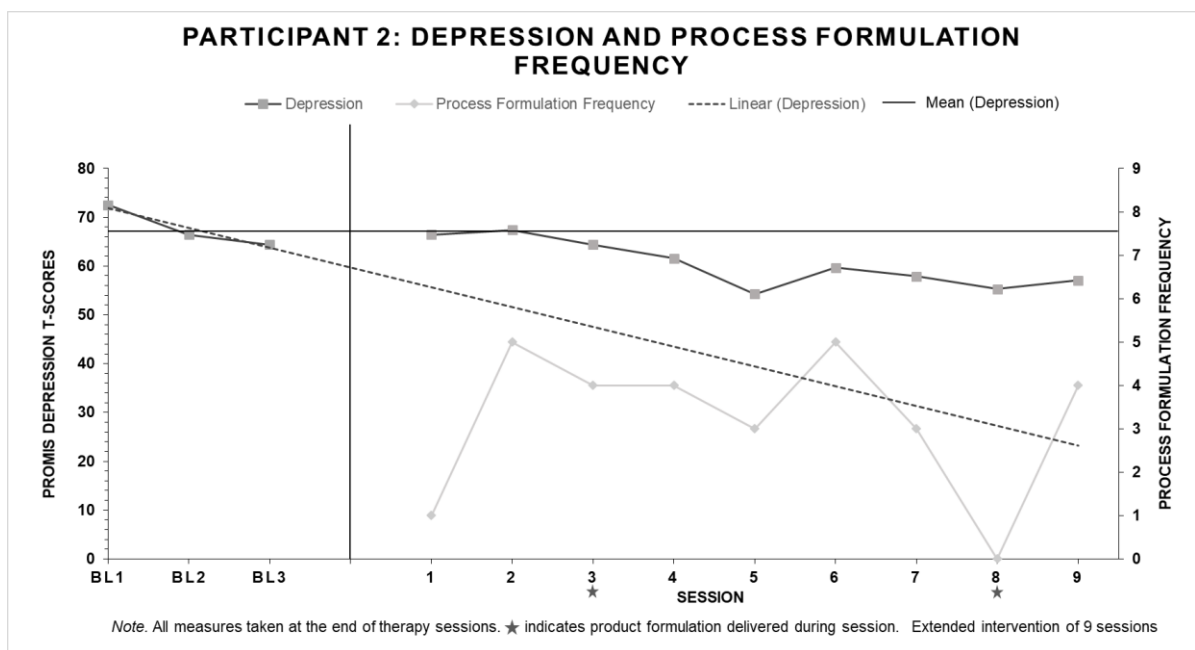
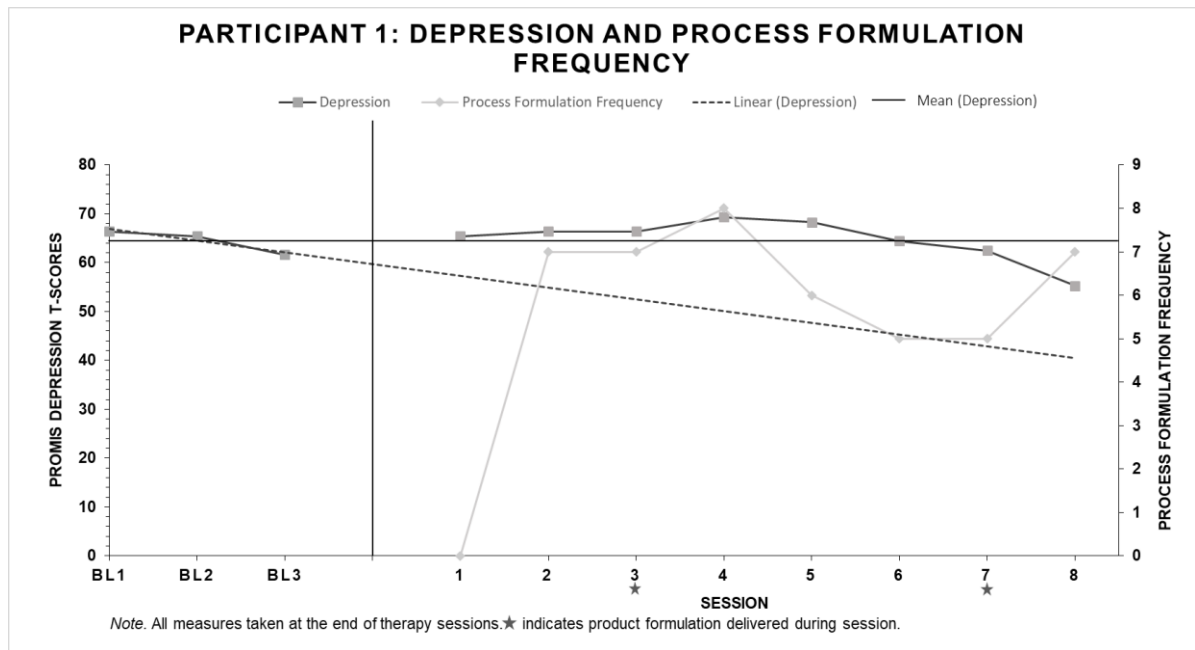


Figure 5. Graphs representing PROMIS Depression and process formulation frequency

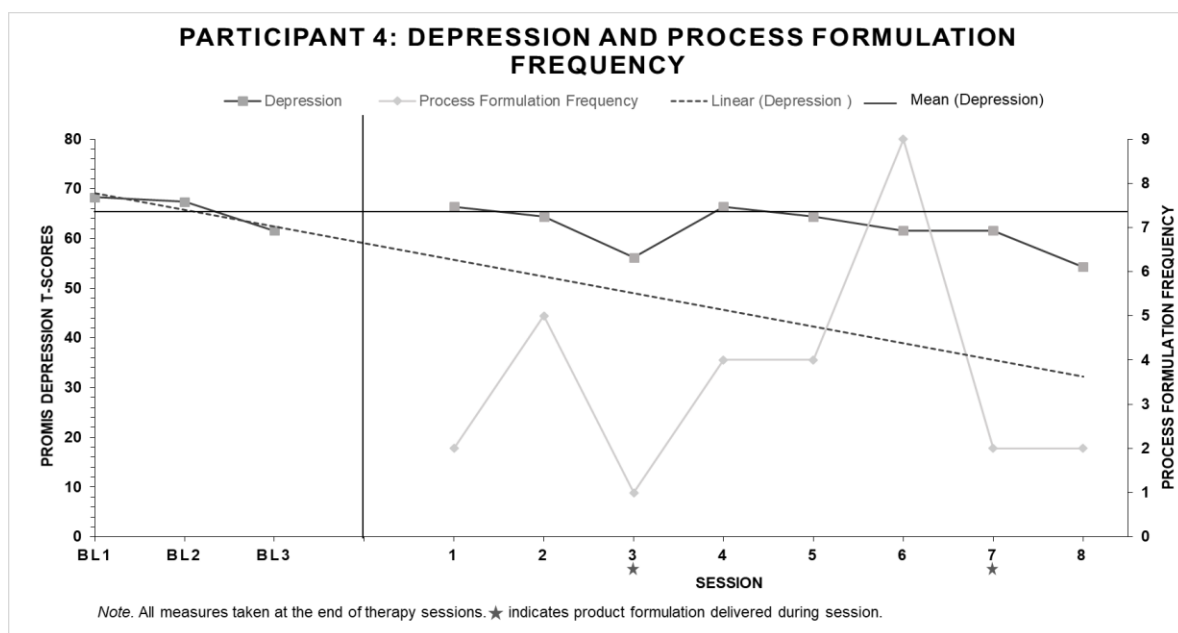
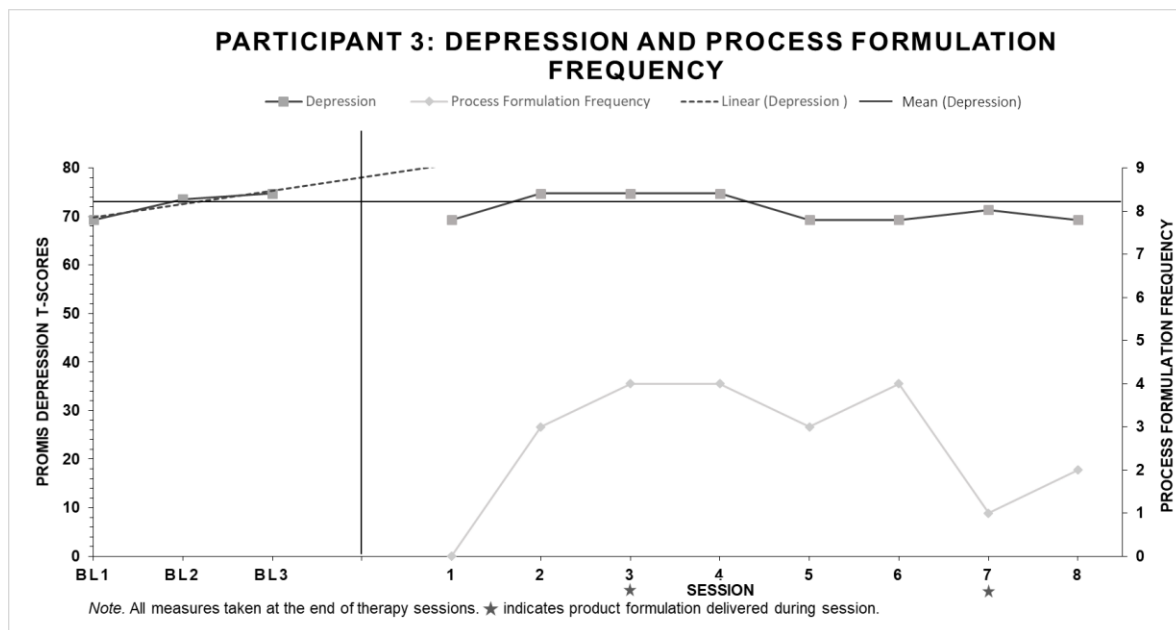


Figure 5 continued. Graphs representing PROMIS Depression and process formulation frequency

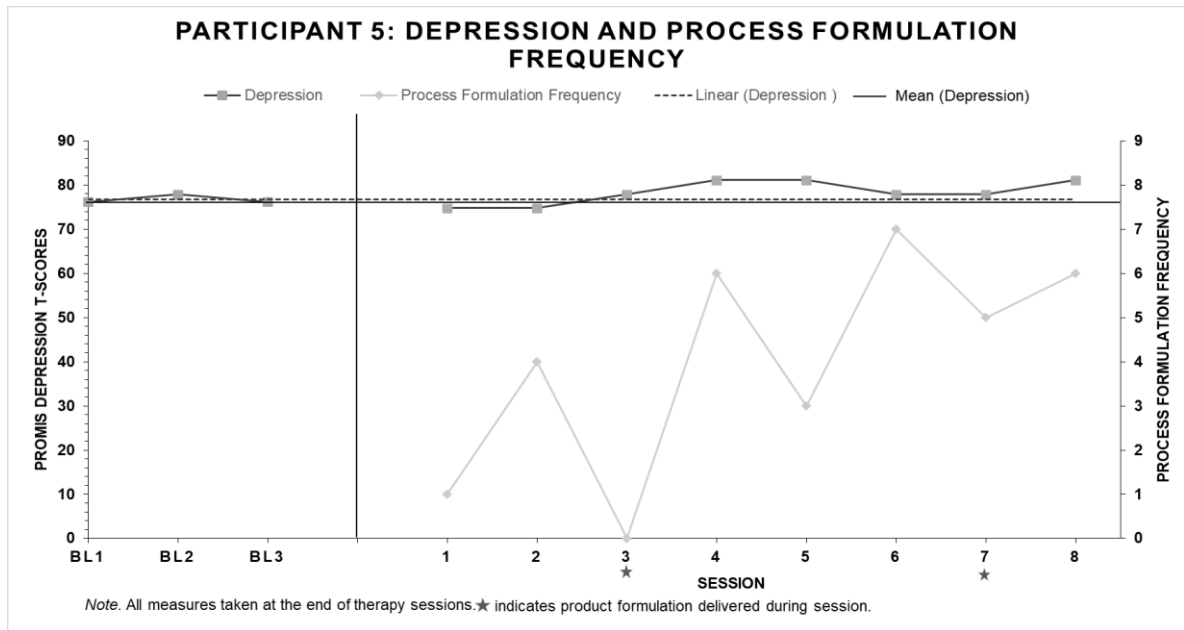


Figure 5 continued. Graphs representing PROMIS Depression and process formulation frequency

SMA was used to analyse the relationship between the frequency of process formulations, depression and well-being (measured on MHC-SF). The analysis showed that for participant one, a higher frequency of process formulations delivered by the therapist preceded a deterioration in depression in the following session (P1, $r = +.81$). However, no further statistically significant correlations were found with any other participant and therefore this does not meet replication criteria. SMA also reported two statistically significant correlations between the frequency of process formulations and a deterioration in wellbeing, although the lags in which correlations were found were inconsistent. For participant two, the analysis showed that an increase in the frequency of process formulations delivered preceded a deterioration in wellbeing in the following session (P2, $r = -0.67$). However, for participant five, the analysis found that a deterioration in wellbeing preceded and increased frequency of process formulations delivered by the therapist in the session afterwards. In summary, no consistent relationship was found between the frequency of process formulations, depression and well-being³¹.

Visual analysis of working alliance data and levels of depression was also undertaken. Graphical displays of the data are illustrated in Figure 6. During the intervention phase, two participants (P2 and P4) showed a worsening trend in levels of depression in parallel to an increase in working alliance, reported by the participant. SMA was undertaken to analyse the relationship between participant and therapist reported working alliance and also participant reported working alliance reported and depression. Table 7 presents correlation coefficients, reporting whether the correlation is statistically significant, the direction of the association (+ or -) and at what lag the association occurred.

³¹ See extended paper section 3.6 for SMA, correlation coefficients for frequency of process formulations, wellbeing, depression and working alliance.

Table 7

Simulation Modelling Analysis: Participant and Therapist Alliance and Participant Alliance and Depression

Participant	Lag	Participant & Therapist Alliance	Lag	Participant Alliance & Depression
P1	+1	$r = +.69^*$	+1	$r = -.49$
	0	$r = +.84^*$	0	$r = -.28$
	-1	$r = +.48$	-1	$r = +.12$
P2	+1	$r = +.48$	+1	$r = -.71^*$
	0	$r = +.75^*$	0	$r = -.74^*$
	-1	$r = +.47$	-1	$r = -.17$
P3	+1	$r = -.03$	+1	$r = +.41$
	0	$r = -.13$	0	$r = +.47$
	-1	$r = -.63^*$	-1	$r = +.20$
P4	+1	$r = +.75^*$	+1	$r = -.61^*$
	0	$r = +.64$	0	$r = -.12$
	-1	$r = +.22$	-1	$r = +.02$
P5	+1	$r = +.17$	+1	$r = +.21$
	0	$r = +.82^*$	0	$r = +.64$
	-1	$r = -.01$	-1	$r = -.08$

Note. * = $p < .05$. + or – indicates direction of correlation (positive or negative).

SMA analysis showed that for three participants (P1, P2 and P5), there was a significant correlation between participant and therapist reported alliance, at a lag of 0 (i.e., within the same therapy session). This is repeated across three cases and therefore meets minimum replication criteria. Also, two participants (P2 and P4) reported significant correlations between an increase in participant reported alliance and an improvement in depression in the following session. However this was not repeated across three participants and therefore does not meet replication criteria. In summary, a strong relationship was found between therapist and participant reported working alliance and a slight relationship was found between participant reported working alliance and improved levels of depression²⁹.

SMA was undertaken on participant reported alliance and levels of wellbeing. Analysis reported one significant correlation (P4), which showed that an increase in participant reported working alliance preceded an improvement in wellbeing in the following session, although this was not repeated at the same lag with any other participant and therefore does not meet minimum replication criteria²⁹.

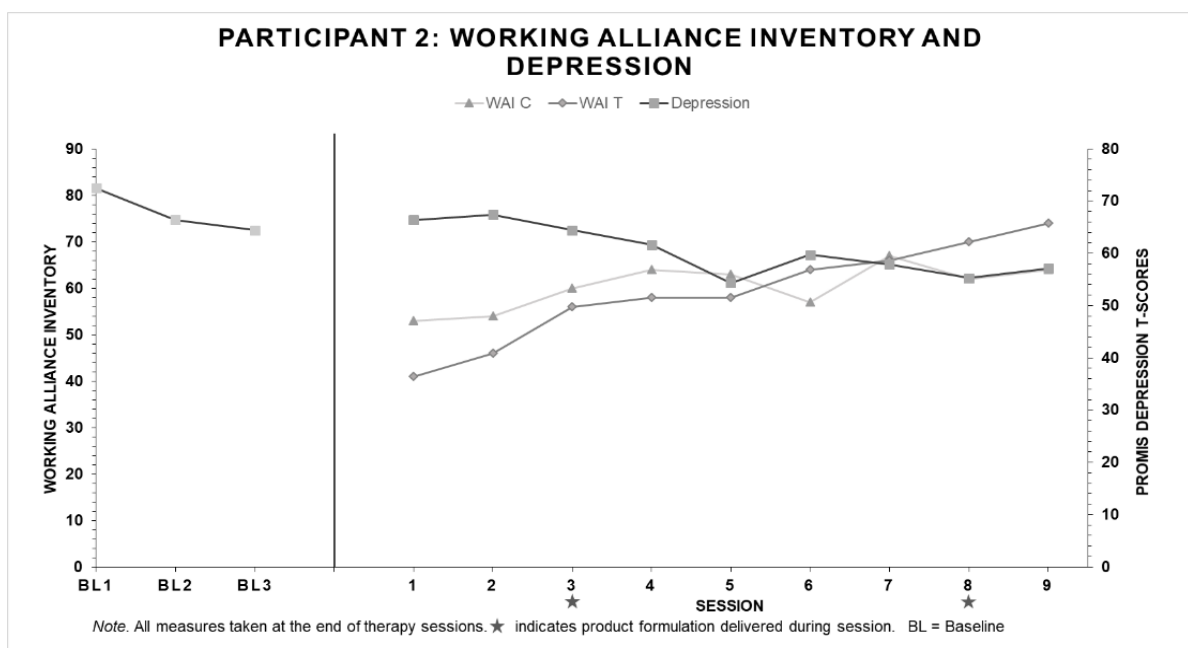
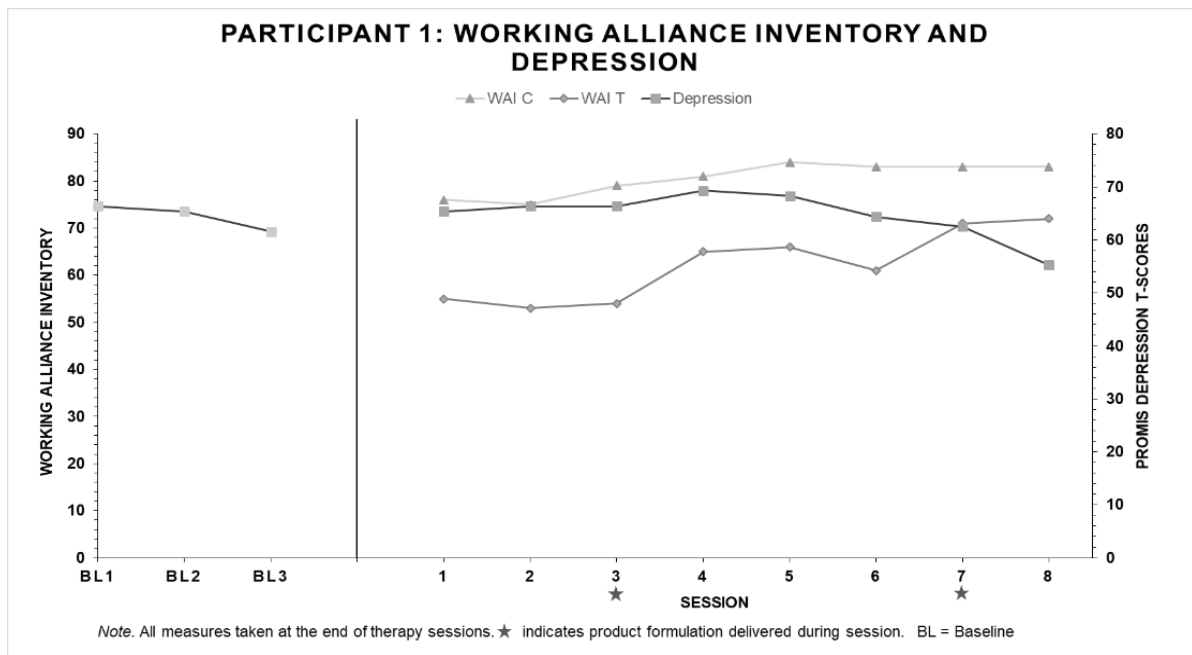


Figure 6. Graphs representing Working Alliance Inventory and PROMIS Depression

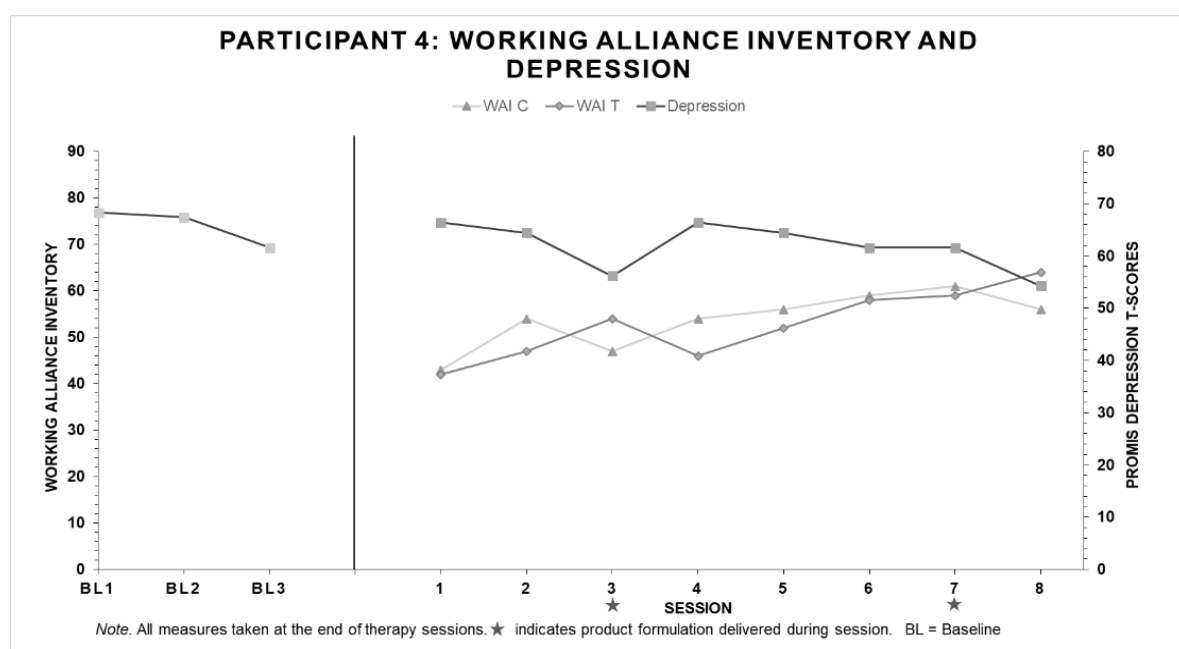
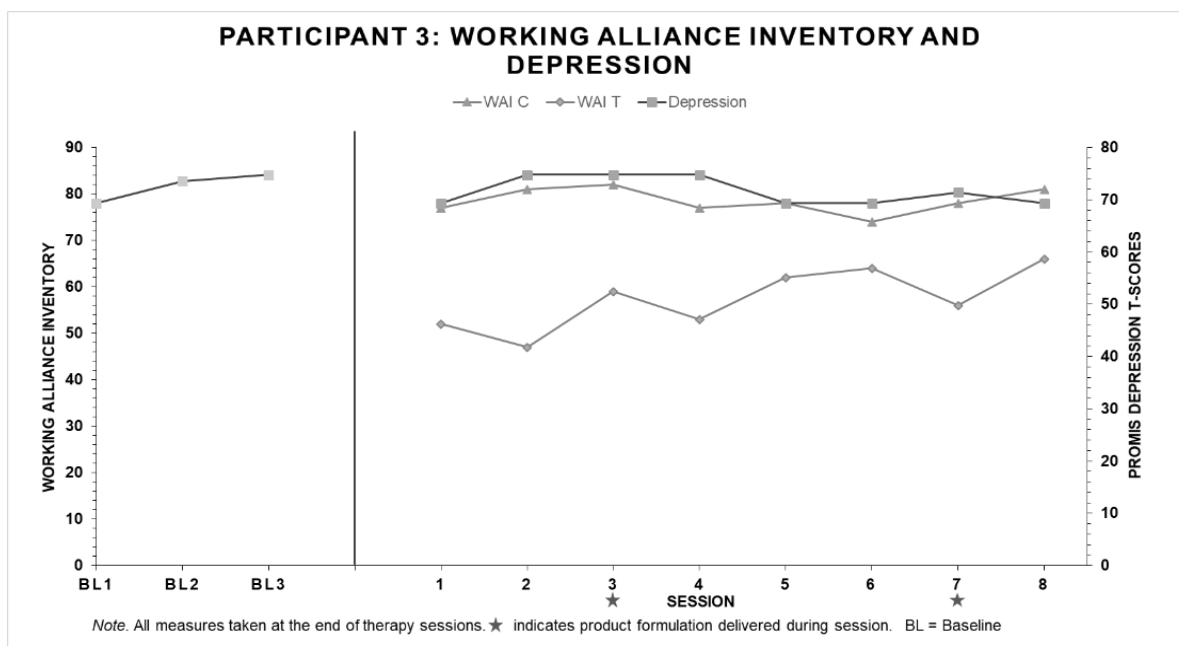


Figure 6 continued. Graphs representing Working Alliance Inventory and PROMIS Depression

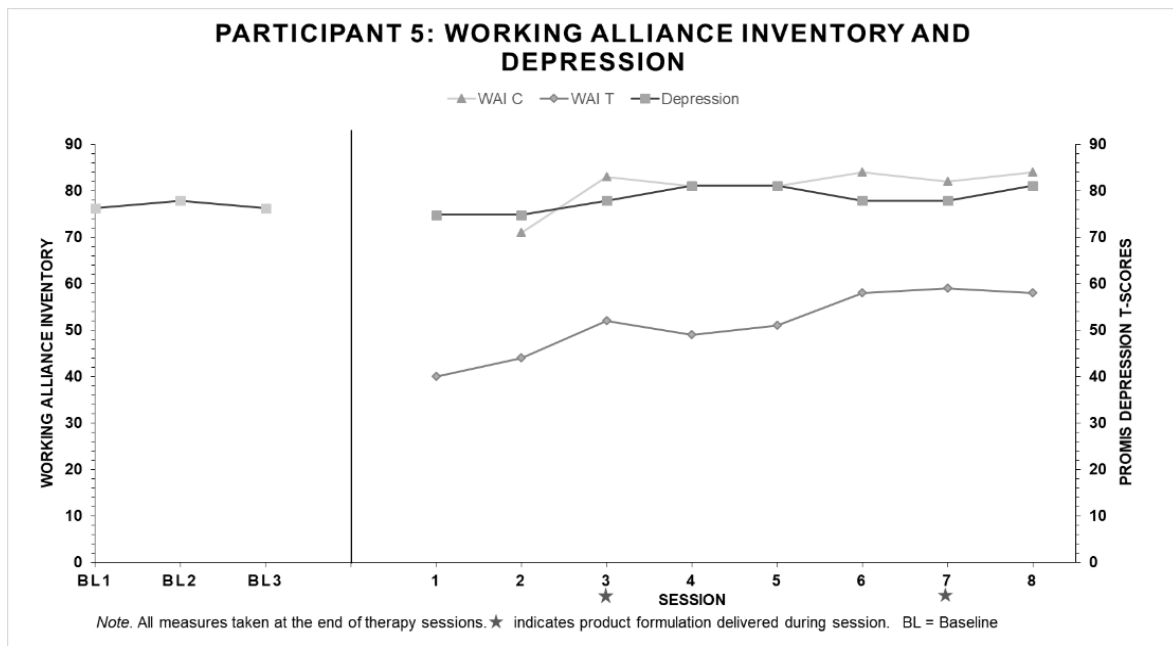


Figure 6 continued. Graphs representing Working Alliance Inventory and PROMIS Depression

RCI and CSC analyses were undertaken on the PROMIS depression, MHC and CORE measures at significant time points throughout the intervention, including pre (session1), post (session 8/9) and at the point the first and second product formulation (session 3 and 7/8) was delivered³². This is presented in Table 8.

Table 8

Reliable Change Index and Clinically Significant Change Analyses

Participant	Measure	Pre Session 1	Product Formulation Session 3	Product Formulation Session 7/8*	Post Session 8/9*
1	PROMIS Dep	65.4	66.4	62.5	55.3 ^R
	MHC-SF	0.71	0.79	1.43 ^{RC}	1.36 ^{RC}
	CORE	69	-	-	46 ^R
2	PROMIS Dep	66.4	64.4	55.3 ^R	57.1 ^R
	MHC-SF	0.93	0.64	2.0 ^{RC}	2.5 ^{RC}
	CORE	50	-	-	35 ^R
3	PROMIS Dep	69.3	74.8	71.4	69.3
	MHC-SF	1.21	1.21	1.14	1.36
	CORE	68	-	-	50 ^R
4	PROMIS Dep	66.4	56.2 ^R	61.6	54.3 ^R
	MHC-SF	1.64	1.43	2.07	2.07
	CORE	57	-	-	43 ^R
5	PROMIS Dep	74.8	77.9	77.9	81.1
	MHC-SF	0.57	0.36	0.14	0.21
	CORE	97	-	-	92 ^R

Note. RCI and CSC calculated using clinical and non-clinical norms in published literature unless standardised norms are available. PROMIS Dep – Reduction in score indicates improvement in depression. Scores reported as t-scores. MHC-SF – Increase in score indicates improvement in wellbeing. Scores report average of total score. CORE – Reduction in score indicates improvement across symptom domains. * P2, product formulations delivered in session 3 and 8 and duration of intervention was 9 sessions. ^R = indicates reliable change. ^C = indicates clinically significant change.

Three participants (P1, P2 and P4) showed reliable change at post intervention on the PROMIS depression measure, although none achieved CSC. On the MHC, two participants (P1 and P2) showed reliable and CSC at the point the second product formulation was delivered, which was further

³² See extended paper section 3.7 for RCI and CSC calculations.

improved at post intervention. Four out of five participants (P1, P2, P3 and P4) made reliable improvements on the CORE measure at post intervention.

Change Interviews

All but one participant (P4) took part in the change interviews. Participant's responses are presented in Table 9 and a summary of responses, relevant to the research questions is provided below.

When asked about helpful aspects of therapy, all participants commented on the positive therapist characteristics, although they did not specifically attribute this to the formulation process. However, participants talked about helpful aspects of the alliance, including feeling understood (P1) and feeling at ease to talk about difficult topics (P2 and P3). The majority of participants also referred to the approach of the therapist being helpful; non-judgemental (P2 and P3), "gentle but direct" and not condescending (P5) were all highlighted.

All participants reported positive changes in therapy, but they did not make explicit links between these changes and the formulation. Furthermore, participants did not attribute these changes to the CBT or to external factors outside of therapy either. Three participants (P1, P2 and P5) referred to changes in their thinking, specifically feeling more able to challenge their thoughts. Two participants described feeling different, "less guilty" (P1) and "more accepting...better in myself" (P3). With regards to changes in behaviour, half of participants (P1 and P3) talked about engaging in more activity, although P1 reported that this improvement had not sustained following the end of therapy. Participants reported less negative changes but two participants reported no change, specifically in relation to their thoughts (P3) and continuing to experience anger (P5). All participants referred to external factors that may explain any changes that have occurred in therapy.

When asked about their experiences of formulation, all participants referred to the process of drawing out the formulation (product) and all but one participant (P1) reported that this was a helpful to make sense of their experiences. Half of participants (P1 and P2) talked about their experience of process formulations, although two participants were not aware of process formulations during therapy.

Three participants (P2, P3 and P5) referred to a negative emotional response in relation to their formulation. Two participants described finding the product formulation "overwhelming" (P2) and "hard to look at...like having to relive it again" (P5), although both felt like the formulation was a helpful process. P3 reported that some of the explanations of the development of her

depression was “not very nice” and described feeling shocked, but overall the formulation aided her understanding.

Half of the participants (P2 and P5) added that they felt the product formulation made more sense the second time it was shared and it was therefore more helpful (P2), although they did not report whether this contributed to changes in their thoughts, feelings or behaviours. P2 specifically felt that if the formulation had been shared during every session, it would not have had the same positive effect.

Table 9

Summary of Participant's Responses from Change Interview

Interview Question	Participant 1	Participant 2	Participant 3	Participant 5
Previous therapy	No previous therapy but watched CBT videos on YouTube.	CBT 7 years ago, but totally different to therapy with Hannah.	No previous therapy.	Counselling.
Influence expectations of current therapy	Open minded as to whether it would help. Tried therapy because I was struggling and had to do something.	Didn't enjoy previous CBT and didn't think current therapy would be any different.	No expectations.	Aware that you have to engage with the person as well as the therapy. Felt apprehensive, but willing to try anything.
Helpful aspects of therapy	She understood me. Her questions were accurate for my personal situation. She encouraged me to do more.	Felt comfortable, she didn't force information out of me, and I told her things I hadn't told anyone before. She wasn't judgemental, it felt like she knew me and that helped. Explanation of why my anxiety happens. She helped me to understand it's okay and normal to feel like I do. Therapy hasn't cured it, it's helped me put things into	Felt easy and I could talk about anything. Helped to understand how I was feeling was normal. Helpful to talk because she never judged me, it felt reassuring	Hannah listened and helped me to see things from other perspectives. Hannah's approach helped, she was gentle but direct and didn't come across condescending.

Unhelpful aspects of therapy	Struggled to follow weekly schedules (going to the gym and going out). Difficult to do them in between sessions.	perspective. Sad therapy ended, it would have been nice to have longer.	Sometimes we didn't agree, but that was okay. I told her I didn't agree and we talked about it.	Therapy was challenging and hard sometimes, but I needed it. I could have done with more time with Hannah.
Any positive changes	Changed how I thought about myself, feel less guilty. I looked at the evidence, it helped me to see I am not a failure. Understood why I felt depressed. I did more things I enjoyed in therapy, this has stopped now.	Challenge my thoughts and I can have a word with myself. Intrusive thoughts are less frequent and understand thoughts are normal.	I wanted more time for therapy. I am more accepting of things. I do more (badminton and things around the house). I feel a bit better in myself and I notice my emotions more.	Try to see other's points of view. Recognise and challenge my black and white thinking. Can process how I feel and let go of bad feelings quicker. Share how I feel more than before.
Any negative changes	None.	None.	My thoughts are still the same.	I still get angry and "blow up" like I used to.
External factors to therapy to explain changes	Personal difficulties towards end of therapy and ongoing at time of interview.	Personal difficulties towards end of therapy and ongoing at time of interview.	Good relationship with peer support worker who I see regularly.	Go to meditation and have a good relationship with nurse.
Experiences of formulation –	Yes	No	Yes	Ongoing difficulties with physical health and pain. No

required a prompt				
Experiences of product formulation	She drew something out with me, but can't remember much.	Writing it down helped to look at it all together and understand my depression and anxiety. We looked at how I was thinking and my beliefs.	Hannah broke it all down. We looked at my past at what caused my depression.	We drew it out; looked at how my thoughts work and how I react. Looked at my past, which helped explain how my thoughts work. The second time, we changed it slightly because of something that happened. Not aware of process formulations.
Experiences of process formulations	This is what the therapy was all about, helping me to see how my behaviour, thoughts and feelings, how they are linked together.	She did these most sessions. At first, I was a bit dubious and didn't think it would be helpful. After a few sessions, it started to make sense and I thought about it after sessions.	Not aware of process formulations.	
Helpful aspects of formulation	Helped me to look at my thoughts, challenge them and see that I shouldn't feel guilty. Helped to understand how I feel about myself. At the time, it felt more helpful. Now I	Drawing it out helped to make sense of thoughts. Felt like a conversation, the formulation didn't feel forced on me.	Writing it down was helpful, seeing it all written down in a diagram, it made sense. Helped me to put things in perspective.	When we drew it out, it helped me get it. Helped to spot how I think, what I do in everyday life and understand why I do what I do. Overall a positive experience.

Unhelpful aspects of formulation	<p>don't know how to use what I learnt in the formulation.</p> <p>None.</p>	<p>When it was drawn out, I felt a bit overwhelmed. It wasn't negative, but seeing everything from my past, it was a shock. It made me think, no wonder I get depressed.</p> <p>Didn't want to take formulation away, because I felt I got it out of my system.</p>	<p>At first I thought "that's not very nice". It was a shock to me, but it did help me to understand my depression.</p>	<p>Sometimes it was hard to look at. It was like having to relive it again and it felt hard to disengage with, because it was in front of me.</p> <p>Seeing it in black and white, it's like confronting a lot of your demons. Sometimes, it felt hard to hear.</p> <p>It wasn't the nicest thing in the world to do, but it wasn't unhelpful, it was a positive experience.</p> <p>Looking at formulation the second time, because we had talked a lot, it made more sense.</p>
Anything else to add.	None.	<p>Looked at formulation in a totally different way the second time. Had a better understanding and knew what it was trying to do rather than bits of information on a piece of paper. Made more sense and it was more helpful.</p> <p>If we had looked at the formulation every session, I don't think it would have had the same effect.</p>	None.	

Note. Hannah = name of therapist.

Discussion

This study aimed to examine whether formulation impacts on working alliance and other secondary outcomes during CBT. The study answered two research questions, each of which are outlined below, considering the findings and making links to existing literature. Finally, a critique of this study is provided, offering recommendations for future research.

Does Formulation Impact Working Alliance?³³

The findings showed a slight relationship between formulation and working alliance, although evidence was not robust enough to confirm whether formulation directly impacts working alliance.

With regards to process formulations, findings showed little evidence to suggest that an increased frequency in process formulations impacted the working alliance. The number of process formulations delivered across participants varied (total ranged 21 – 45). This variability may provide an internal consistency check, as the delivery rate of process formulations differed across participants (i.e., participants received varied doses of formulations), which means if there was an effect to be found it would be more easily detected. Variability could be indicative of an improved working alliance, creating a safe space where the therapist feels better able to deliver a greater number of formulations. Contrary to this, it could also be that when the therapist perceived the alliance was weak or the client's understanding was limited, this resulted in a compensatory effort to foster engagement and coherence, thus the therapist delivered a higher frequency of process formulations. The receptiveness of the client is also important and may influence the number of formulations the therapist delivers. In this study, participant three was particularly talkative, allowing less room for the therapist to deliver process formulations (total frequency = 21). Finally, it might be that supervision may increase the therapist's confidence to deliver more formulations throughout therapy. These explanations of variability are simply hypotheses as to why there was such variability in the frequency of process formulations. As this was not measured in the current study, it may provide a recommendation for future research.

Psychodynamic literature suggests that a higher frequency of interpretations offered in therapy improves the working alliance and importantly this is mediated by the client's perceived level of accuracy (Crits-Christoph,

³³ See extended paper section 4.1 for further discussion answering does formulation impact working alliance.

Barber, & Kurcias, 1993). In the current study, SMA reported statistically significant correlations for two participants, showing that an improvement in participant reported working alliance preceded an increase in the frequency of process formulations delivered in the following session. It is important to note the limitations of SMA conducted in this study when interpreting findings. Identifying lagged correlations between the frequency of process formulations and the working alliance are likely to be confounded by sessions when a product formulation was delivered. This is because fewer process formulations were offered but a formulation was delivered in a different, unmeasured form (i.e., sessions may inaccurately reflect the 'dose' of formulation delivered). As process formulations were delivered more subtly during therapy, it was difficult to obtain participant's experiences of them during the change interviews. The quality and accuracy of formulations is vital when understanding the impact formulation has on working alliance. When measuring formulation using a bottom-up approach, it is important we consider how client's receive the formulation (i.e. is the formulation helpful for them) (Kuyken, Fothergill, Musa & Chadwick, 2005). This emphasises that the client's perceived accuracy of the formulation is essential, as this may drive or hinder the working alliance. For example, if a therapist delivers a high frequency of process formulations, which the client perceives as an inaccurate reflection of their experiences, this may rupture the alliance. The accuracy of formulations delivered was not measured and therefore cannot be considered when drawing conclusions, which highlights a potential limitation of this study.

In relation to the product formulation, therapist's measure of working alliance showed a slight peak at the point the second product formulation was delivered for three participants, although this was not reflected in participant's responses on the WAI. Peaks observed in working alliance reported by the therapist were very slight and not the only peaks noted during the intervention, therefore this should be interpreted tentatively. Nevertheless, there is inconsistency between the therapist and participant's reports of working alliance at the point the second formulation is delivered. This supports Chadwick and colleagues (2003) findings that therapists report an improved alliance when delivering a formulation, which was not reflected in participant's responses, suggesting that formulation may be more beneficial for therapists rather than clients. In this study, it is not possible to attribute therapist's responses on the WAI with the product formulation delivered during the session and other explanations must be considered. Several studies have examined the development and decay of the working alliance during time-limited therapies, which proposed a 'curvilinear pattern'; an initial high level, which declines during a conflictual period and then subsequently recovers towards the end of therapy (Gelso & Carter, 1994; Horvath & Marx, 1990). However, in practice there are

considerable variations, for example, when working with complex clients, alliance ratings tend to be lower for longer throughout the initial phase of therapy (Kivlighan & Shaughnessy, 2000). This hypothesis may offer one explanation for the peak in therapist's reports of working alliance during the penultimate session of therapy (when the product formulation was delivered). As the study design did not include post-therapy interviews with the therapist, it is not possible to tease this apart further.

Consistent with previous research (e.g., Chadwick, Williams & Mackenzie, 2003; Evans & Parry, 1996; Rayner, Thompson & Walsh, 2011), participants described the formulation process as helpful, enabling them to "make sense" and have a "better understanding of their difficulties", however, this study showed little evidence to confirm whether formulation directly impacts working alliance. Teasing apart the formulation component from other aspects of therapy, such as the CBT intervention is a challenge. Formulation is embedded into psychological interventions, such as CBT, and consequently is difficult to separate from other psychotherapeutic techniques. Referring back to the definition of formulation, a tool which applies psychological theory to make sense of the development and maintenance of an individual's difficulties (Butler, 1998; Johnstone, 2006), it is conceptually and clinically problematic to disentangle this from CBT techniques, such as, a cognitive challenge or setting up a behavioural experiment. Overlap in these processes creates uncertainty as to whether the formulation and, or the CBT intervention is driving the working alliance during therapy.

What is the Relationship between Formulation, Working Alliance and Psychosocial Outcomes?³⁴

Data showed mixed findings in terms of the relationship between formulation, working alliance, and the psychosocial outcomes measured. Although over half of participants showed an improvement in depression, two showed improvements in wellbeing and the majority improved across a range of symptoms on the CORE-OM, it is not possible to attribute these changes solely to formulation. Factors such as the CBT intervention may have contributed to these improvements, although the study design did not specifically measure aspects of CBT that are expected to change (e.g., thinking styles), which would have helped to distinguish whether it was the CBT intervention, or other factors (e.g., non-specifics) that impacted on outcomes. However, during the change interviews participants did comment on changes that are reflective of CBT,

³⁴ See extended paper section 4.2 for extended discussion on answering what is the relationship between formulation, working alliance and psychosocial outcomes.

including changes in thinking (e.g., “challenge my thoughts...recognise and challenge my black and white thinking”), behaviour (increase in levels of activity) and their emotional state (e.g., “feel less guilty...more accepting”). Although the authors cannot be conclusive as to whether changes can be explained by the CBT intervention, process of formulation or the working alliance, it is important to highlight that the language used by participants mirrors that of CBT. However, existing research suggests that the alliance is the strongest predictor of outcome in therapy (Duncan, Miller, Wampold & Humble, 2010; Horvath, Del Re, Flückiger & Symonds, 2011) and therefore should be considered when drawing conclusions.

Results showed mixed findings between formulation, levels of depression and wellbeing. SMA reported one significant correlation, showing that an increased number of process formulations delivered preceded a deterioration in depression in the following session, although minimum replication criteria was not met which limits the generalisability of this finding. As previously discussed, it is difficult to ascertain whether a deterioration in depression is a result of process formulations delivered or other specific and non-specific factors in therapy. Consistent with previous research (Chadwick et al., 2003; Evans & Parry, 1996; Pain, Chadwick & Abba, 2008; Rayner et al., 2011), qualitative data revealed three participants experienced a negative emotional response when provided with the product formulation. Supporting this finding, outcome measures showed a worsening in depression for two of these participants (P3 and P5) when the product formulation was delivered (on both occasions). Formulation is core to our clinical practice (DCP, 2010), although this finding along with previous research highlights that we must remain aware of potential negative reactions and deliver formulations sensitively. If an effective working alliance is established, it should be expected that difficult emotions reported by clients (e.g., feeling overwhelmed, shocked, reliving) are explored using the safety of the client-therapist relationship. All participants who described negative emotions in response to the formulation commented that this did not alter their views that the formulation was a helpful process. Johnstone (2018) commented that previous research is unclear regarding the permanence of client's negative reactions to formulation, although this study offers some evidence to suggest that they are followed by a more positive trajectory. Additionally, two participants commented that the product formulation was more helpful at the second point it was delivered during the intervention, although they did not specify how it was more helpful. Regardless, this may offer valuable reflections for clinical practice and highlights that the point in which a formulation is delivered may alter how clients receive and utilise it.

Consistent with previous literature examining the trajectory of working alliance in therapy (Gelso & Carter, 1994), all but one participant showed an

upward trend on the WAI, which was supported by participant's responses in the change interviews, commenting on the value and key features that the therapist contributed to the alliance (e.g., non-judgemental, comfortable, feeling listened to and understood). The common factors model emphasises the importance of the alliance and suggests a relationship between a stronger working alliance and improved outcomes (Horvath et al., 2011; Wampold, 2001). SMA showed a significant correlation, at a lag of +1, between two participant's measure of working alliance and improved levels of depression. This may reflect previous research (Horvath et al., 2011), but as minimum replication criteria was not met, this study cannot conclude whether there was a relationship between working alliance and outcomes. Findings do provide evidence that the alliance was an important process for participants; however the results from this study have not concluded any clear relationships between variables.

Strengths, Limitations and Future Research³⁵

This study is the first attempt at measuring the impact of CBT formulation on working alliance and secondary outcomes, using a mixed methods, repeated single case design. As outlined in previous literature and therefore expected, there were several challenges the researchers faced when attempting to answer the research questions.

Perhaps the most significant challenge of the study was to disentangle such complex process and draw conclusions as to which variables contribute to which changes during therapy. As previously outlined, this study did not measure aspects of CBT that were expected to change, for example, behaviours or thinking styles, which may have aided the researcher to differentiate between which variables impacted on the outcomes. Single-case designs allow researchers to investigate complex processes (Morgan & Morgan, 2008), using a systematic and scientific methodology, although difficulties are still faced when attempting to separate processes. This study highlights overlap between the concepts of formulation, CBT and working alliance. The process of formulation in therapy may enact components of the working alliance, for example, establishing a collaborative understanding of an individual's difficulties (formulation) may replicate the development of the bond component of the working alliance (Bordin, 1979). Additionally, formulation is embedded into psychological interventions and can be delivered subtly (process) as well as more explicitly (product), which often makes it difficult to

³⁵ See extended paper section 4.3 for extended discussion on limitations and challenges and 4.2 for further detail on strengths and implications for clinical practice.

separate out from the intervention. As previous literature suggests (Andrusyna et al., 2001), conceptually CBT and working alliance share key components and consequently it is problematic to disentangle the two. Introducing the product formulation at various time points, between different participants may have enabled the researcher to draw firmer conclusions as to whether the formulation contributed to any changes in outcome.

Another limitation of the study was the dual role of the therapist and researcher, however, several methods were used to manage this, including, supervision, second coding, and keeping reflective notes. Although the therapist was a Trainee Clinical Psychologist and acknowledges her preference to formulation, existing literature on formulation does not conclude any directional impact on outcome, therefore any bias to influence outcomes in this study would have been very difficult. Considering the evidence of poor inter-rater reliability of formulation (Flinn et al., 2015), one therapist was used throughout the study, to improve reliability across the CBT intervention and formulations. Research proposes that different therapists may be more or less able to develop a working alliance, which would impact on outcomes of therapy (Baldwin, Wampold, & Imel, 2007). To test this hypothesis and further examine the impact of working alliance, this study may have benefitted from having more than one therapist, however a cost of this would possibly have been reduced reliability of the formulation and CBT intervention.

Despite some of the limitations discussed here, this study provides a strong attempt at measuring the impact of formulation on the working alliance and psychosocial outcomes. The design has considered some of the conceptual and measurement challenges which have been highlighted in the literature (BPS, 2011). Also, the study tested formulation using scientific and robust methodologies, within a naturalistic setting which is most generalisable and useful for clinical practice. This is a significant strength of the study, as there is very little published research that has attempted to do this and therefore offers a valuable contribution to the field of clinical psychology.

Conclusion

In summary, this study contributes to a dearth in the literature surrounding the impact of psychological formulation on outcomes in therapy, specifically the working alliance. The findings show a mixed and complex picture and although tentative conclusions can be made that formulation, particularly the product formulation, may have contributed to feeling listened to

and understood, it is not possible to say that this directly impacted on the working alliance. This study also supports previous literature that individuals may have mixed emotional responses to the formulation, including feeling overwhelmed and shocked (Chadwick et al., 2003; Evans & Parry, 1996). However, in answer to Johnstone's (2018) reflection, it does not seem that these negative responses are permanent and they seem to be managed and worked through using the vehicle of the working alliance.

Similarly to any area of psychotherapy research, this study highlights the complexity of disentangling processes to draw conclusions on what variables contribute to changes in outcomes, i.e. can we separate the impact of formulation from the specifics of the CBT intervention or the non-specifics in the working alliance? Additionally, it is important to consider the overlap in the concepts of the working alliance, formulation and the CBT intervention. Considering the key components of the concept of working alliance; bond, task and goal (Bordin, 1979), is it possible to deliver a CBT intervention, without contributing to the alliance, nor is it possible to develop a formulation without impeding on the alliance? Despite the complexity of this, it offers interesting and valuable reflections, which hopefully provides a platform for future research into formulation.

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Extended Paper

1. Extended Background

1.1 Conceptualisation of Psychological Formulation

The definition of psychological formulation varies across professions, the therapeutic modality used and how a therapist delivers a formulation during therapy (BPS, 2011). The literature often defines formulation as a hypothesis, developed using psychological theory, which provides an explanation of an individual's difficulties (BPS, 2011; Johnstone & Dallos, 2006). Additional commonly referenced definitions include; "a process of ongoing collaborative sense-making" (Harper & Moss, 2003, p. 8), "a way of summarising meanings, and of negotiating for shared ways of understanding and communicating about them" (Butler, 1998, p. 4). Dependant on the therapeutic model, the label used and delivery of the psychological formulation differs. For example, in CBT, the term psychological or case formulation is used, in Cognitive Analytic Therapy (CAT) the process is referred to as reformulation and in psychoanalytic therapy, formulations are delivered as an interpretation. For consistency, this study uses the terms psychological formulation or formulation for short.

1.2 Background and Context of Psychological Formulation in Clinical Psychology

The origins of psychological formulation as a core skill of the profession can be traced back to the 1950s (BPS, 2011). However, prior to this Freud's writing discusses the process of constructing personal meaning out of mental distress, for example, "case histories I write should read like short stories...case studies of this kind have, however, one advantage...namely an intimate connection between the story of the patient's sufferings and the symptoms of his illness" (Freud & Breuer, 1974, p.231). Influential clinicians including Hans Eysenck and Monte Shapiro used key components of operant and classical conditioning to develop individualised alternatives to using psychiatric diagnoses (BPS, 2011).

The term 'formulation' was first referenced in clinical psychology guidelines in 1969 (Crellin, 1998) and is now a familiar term, not only within clinical psychology but across psychiatric settings (Johnstone, 2018). Formulation has been referred to as the cornerstone of clinical psychology and is one of nine core competencies, outlined by the British Psychological Society (BPS, 2010) which must be evidenced throughout training and clinical practice. Formulation is a core competency in clinical psychology training and practice and also features in the curriculum for psychiatry training and has recently been introduced into the Core Mental Health Skills Education and Training Framework, which is applicable to all mental health professionals in England.

The BPS and DCP have promoted formulation as an alternative to diagnosis for some time (Johnstone, 2018). Several documents published by the BPS and DCP discuss the significant limitations of diagnosis and highlight the value of using formulation to develop a holistic, non-medicalised understanding of mental health difficulties. Key documents include; the Power Threat Meaning Framework (BPS, 2018), DCP position statement on psychiatric diagnoses (DCP, 2013) and Good Practice Guidelines on the use of Psychological Formulation (BPS, 2011). Some of the limitations of diagnosis and the alternative of psychological formulation are discussed below.

1.3 Psychological Formulation as an Alternative to Diagnosis

Formulation offers one possible alternative to the criticisms that psychiatric diagnostic classification systems have received over many years. Psychiatric diagnoses have been criticised for lacking reliability, validity, contributing to stigma and excluding the consideration of social and cultural contexts (Bentall, 2009; Boyle, 2002; Kirk & Kutchins, 1997). Psychiatry considers mental health as a branch of medicine and understands the concept of human distress using a disease model (Boyle & Johnstone, 2014). As a result, psychiatric diagnoses have been criticised for the negative impact they can have on the individual as they can turn "people with problems" into "patients with illnesses" (Johnstone, 2018). It is suggested that diagnosis can contribute to a "loss of meaning" within an individual's experiences, as the personal, social

and cultural context are overshadowed by the diagnostic label (Johnstone, 2014). Although diagnoses can be helpful for individual's to name their distress, this is unsupported by empirical evidence and the majority describe feelings of shame, worthlessness and hopelessness (Johnstone, 2014). It is unclear how researchers have been able to isolate variables associated with mental ill-health from the awarding of a diagnosis. Given that shame, hopelessness and worthlessness are already key characteristics of many conditions, such as depression, it is uncertain how this is separated from the individual's experience of receiving a diagnosis.

In comparison to diagnosis, formulation pays less attention to the individual's deficits and focuses on their strengths and resilience during times of extreme challenges. Also, formulation approaches any form of psychological distress on the premise that "at some level it all makes sense" (Butler, 1998, p. 2). Johnstone (2006) argues that formulation provides meaning to the content of an individual's distress; whereas diagnosis removes the meaning behind the distress.

Scott and Sembi (2006) propose that the process of formulation and diagnosis do not need to be mutually exclusive of each other, suggesting that diagnosis helps focus and informs the material that is considered in the formulation. This notion is also supported by Eells (2002), who advocates that formulation provides a link between diagnosis and treatment and therefore rather than being two separate processes, they should support each other. The idea of compatibility between formulation and diagnosis is disputed and many argue that formulation provides an alternative to diagnosis, rather than an addition that should be used concurrently (Carey & Pilgrim, 2010). Despite the ongoing debate between formulation and diagnosis, it is clear that both approaches have strengths and limitations which should be considered when delivering them with clients. Within clinical psychology, there has been a clear shift away from diagnosis and the focus has been placed on the value psychological formulation has in the profession. Despite the enthusiasm for formulation, the evidence for its reliability, validity and utility is lacking.

1.4 Research on Formulation

1.4.1 Formulation and Psychosocial Outcomes.

A small number of studies (Chadwick, Williams & Mackenzie, 2003; Evans & Parry, 1996; Thew & Krohnert, 2015) which have measured the impact formulation has on psychosocial outcomes in therapy have shown very little evidence to support a relationship between variables. Chadwick et al. (2003) found no significant difference in participant's anxiety and depression after sharing a CBT formulation over two sessions. In a second experiment, Chadwick and colleagues used a single case series design which found that when the formulation was delivered over four separate sessions, the results showed no significant impact on the strength of delusions or negative self-evaluations.

Evans and Parry (1996) used a multiple baseline across subjects design to examine the short-term impact of reformulation in CAT with four participants. Similarly to Chadwick and colleagues, results showed that the reformulation had no impact on outcomes (participant's perceived helpfulness of sessions, therapeutic alliance and individual problems). One limitation highlighted by Evans and Parry (1996) was that the study focussed on sessions immediately following the reformulation and therefore failed to consider that the process of reformulation may have started as early as session one, when the therapist started collecting information. This raises a challenge when measuring formulation, as to specifying when the formulation process begins, which emphasises the importance of clearly operationalising formulation and how it will be measured during therapy.

Thew and Krohnert (2015) presented a single case report, which used three outcome measures pre and post the delivery of a diagrammatic CBT formulation. Results showed that there were no significant differences in outcomes following the formulation; however the methodology was unclear as to when the measures were administered. A major limitation of this study was the lack of a rigorous design and methodology which meant that little conclusions could be made.

As discussed, each of the studies reported here attempted to measure whether delivering a psychological formulation during therapy impacted on psychosocial outcomes. A limitation which these studies share is the difficulty in separating the formulation from other processes, such as the intervention or the alliance between the client and therapist during the intervention. Additionally, identifying when the process of formulation begins and ends is essential when measuring the impact formulation has on outcomes. This highlights the importance of ensuring a robust, systematic and scientific methodology so that where possible, some of these processes can be separated.

1.4.2 Formulation and the Therapeutic Relationship.

Four published studies (Chadwick et al., 2003; Crits-Christoph, Jacques, & Kurcias, 1993; Evans & Parry, 1996; Shine & Westacott, 2010) have also measured the impact formulation has on the therapeutic relationship, all of which show little evidence to support a relationship between the process of formulation and the therapeutic relationship.

As previously discussed, Chadwick et al. (2003) investigated the impact formulation has on psychosocial outcomes and they also measured client and therapists' ratings of the therapeutic alliance two sessions before and two sessions after a CBT formulation was delivered. Results showed that although clients' ratings of the alliance increased over the course of therapy, this was probably attributable to a general increase in therapeutic alliance expected during therapy and could not be attributed to the formulation. However, therapists rated the therapeutic alliance as higher than participants between time points when the formulation was delivered, although it was uncertain as to whether this was as a result of the delivery of the formulation or other specific and non-specific factors. The authors highlight that the formulation had an impact on therapist's alliance ratings and therapist's comments confirmed that the formulation could be a "validating experience", although this was not supported by participant responses. This raises the idea that the delivery of formulation during therapy may have more of an impact on the alliance for

therapists rather than clients, which questions who benefits from the process of delivering a formulation. It could be that formulation is a clinical tool which builds confidence for the therapist and therefore from the therapist's perspective improves the alliance, although this hypothesis has not yet been researched.

Evans and Parry (1996) and (Shine & Westacott, 2010) both used a single-case series design and measured the impact of reformulation on the therapeutic alliance during CAT. Both studies used visual analysis, although little detail of the analysis and interpretation is provided to support their conclusions that there was no change in therapeutic alliance after the formulation was delivered. Crits-Christoph et al. (1993) also found that an increased level of perceived accuracy was correlated with improved alliance, however, due to limitations in the design of the study, no causal links could be established.

Each of the studies discussed here share a similar limitation when attempting to disentangle the alliance from other specific and non-specific processes during therapy. Limitations such as this and the small sample sizes used means that existing literature cannot conclude whether delivering psychological formulation impacts the alliance.

1.4.3 Client's Experiences of Formulation.

Eight studies have explored client's experiences of formulation, which overall show mixed results (Chadwick et al., 2003; Evans & Parry, 1996; Kahlon, Neal, & Patterson, 2014; Rayner, Thompson & Walsh., 2011; Pain, Chadwick, & Abba, 2008; Redhead, Johnstone, & Nightingale, 2015; Shine & Westacott, 2010; Thew & Krohnert, 2015). Of these studies, four used a qualitative methodology (Kahlon et al., 2014; Rayner et al., 2011; Redhead et al., 2015; Pain et al., 2008) and four included semi-structured interviews within a mixed methods design (Chadwick et al., 2003; Evans & Parry, 1996; Shine & Westacott, 2010; Thew & Krohnert, 2015). All studies reported that participants described formulation as a positive experience, particularly contributing to feelings of optimism and a sense of relief. For some participants, this was as a result of receiving an explanation of their difficulties which was pertinent to

feeling understood (Kahlon et al., 2014; Redhead et al., 2015; Shine & Westacott, 2010). In comparison, all but one study (Thew & Krohnert, 2015) also discussed the negative experiences of formulation, which detailed a range of negative emotional reactions experienced by participants when receiving a formulation. These included feelings of 'sadness' (Chadwick et al., 2003; Rayner et al., 2011), 'overwhelmed' (Evans & Parry, 1996), 'a bit daunting' (Pain et al., 2008) and 'worried' (Chadwick et al., 2003).

Negative emotional experiences seemed to be as a result of a process of realisation, an increased awareness of difficulties that had been suppressed or actively avoided by the participant (Kahlon et al., 2014; Redhead et al., 2015). This process of realisation supports the idea initially suggested by Eells (2007), that formulation may hinder a client's engagement due to a conflict between hearing or seeing the content of the formulation delivered and a suppressed understanding into their difficulties. Although this discomfort might be a necessary transition to move through in order to progress through recovery, without further research it is impossible to draw any firm conclusions.

1.5 Reliability and Quality of Formulation

Research investigating the reliability of formulation can be dated back to 1966, when Philip Seitz studied the reliability of psychoanalytic formulations. His study found that there was little agreement across formulations and that therapists were inclined to rely on their intuitive impression without checking the accuracy of these. In a major review, Bieling and Kuyken (2003) found that research has predominately focussed on the inter-rater reliability of formulations and less attention has been given to test-retest reliability to assess whether formulations remain stable over time. In a recent review of the literature conducted by Flinn, Braham and das Nair (2015) found that the reliability of case formulations varied from 'slight to substantial' (.1 - .4 and .81 – 1.0) and reported that studies have shown that reliability in formulations can be achieved across a range of therapeutic models. This review highlighted the varied reliability of formulation across studies and also raised several challenges, including the variation in how formulation is defined and delivered (depending

on the theoretical orientation and the preference of the clinician) and a diverse range of methodologies used across studies, which generates difficulties when drawing conclusions.

There is little clarity of how to assess the quality of formulation (i.e., minimal guidance and a lack of quality assessment tools) and therefore there is disagreement over what constitutes a good quality formulation (Flitcroft, James, Freeston, & Wood-Mitchell, 2007). When scientifically measuring the impact of formulation, both reliability and quality of the formulation are essential considerations (Bieling & Kuyken, 2003). In a review undertaken by Kuyken et al. (2005), they comment that although research has predominately focussed on the reliability of formulation, this may have little value if the quality of the formulation is poor. For example, a formulation might be replicable, but this may have little significance if it is theoretically incoherent or it is unhelpful for the client.

There are very few published tools to assess the quality of formulation. Perhaps the most utilised is the 'checklist of good practice in the use of formulation', published by the BPS (2011). Although this checklist is accessible to researchers and clinicians, it is unclear how the checklist was developed and there is little detail to support its utility, which may result in subjective scoring. Prior to this, Eells, Kendjelic, and Lucas (1998) developed the Case Formulation Content Coding Method (CFCCM), a cross-theoretical tool, which assessed quality by categorising the information a clinician used when developing a case formulation. The CCFM has been used in several studies (Eells et al., 1998; Kendjelic & Eells, 2007) and has shown to be a reliable and clinically useful tool (.60 - 1.0) (Eells et al., 2011). The Quality of Cognitive Case Formulation Rating Scale (Fothergill & Kuyken, 2002) is also referenced in the literature (Kuyken et al., 2005), although the scale remains unpublished and is therefore inaccessible to clinicians and researchers.

1.6 Evidence Based Practice and Practice Based Evidence

It is well established in the literature, that the evidence to support the use of formulation as an intervention is lacking (Aston, 2009) and therefore it has a

minimal evidence-base. However, psychological formulation is frequently used within the National Health Service (NHS) and psychologists are at the forefront of promoting its utility. Amongst other healthcare professionals, clinical psychologists hold Evidence Based Practice (EBP) in high regard and are committed to delivering practice which is grounded in the best evidence. There is a clear discrepancy between psychologists using formulation, which has a minimal evidence-base and placing value on EBP, which raises the question as to why psychologists use formulation in practice. As previously discussed (in section 1.4.2, Formulation and the Therapeutic Relationship), it could be that psychologists find that formulation improves their confidence in their practice or they feel it has value to establish the working alliance (i.e. Practice Based Evidence; PBE), although there is little evidence to support this. The economic climate of the NHS is placing ongoing pressure on professionals to sell themselves and prove their worth. Clinical psychologists brand the skill of formulation as unique and core to the profession, which emphasises the need to prove what they are doing is effective, for example, that formulation is contributing to positive outcomes. As outlined as a recommendation by the BPS (2011), further research into formulation is required.

1.7 Common Factors Approach

Given that this study aims to examine the impact of formulation on working alliance and the relationship between formulation, working alliance and psychosocial outcomes, it is important to consider the literature surrounding common factors, specific factors and Empirically Supported Treatments (ESTs).

How the term 'common factor' is currently used in the literature is inconsistent and therefore confusing (Lampropoulos, 2000). The 'common factors approach' focuses on factors that are required and sufficient for change to occur in therapy. Wampold (2001) outlines five common factors, which are all necessary ingredients for efficacious interventions (see Table 2). In comparison, specific factors solely focus on the technical components of the therapeutic process (i.e., psychotherapeutic techniques). For example, in CBT, specific factors refer to techniques such as, socratic questioning, guided

discovery and thought challenge. In summary, common and specific factors focus on different aspects and levels of the therapeutic process.

The discussion about common factors in psychotherapy was initiated after an article published by Saul Rosenzweig (1936) suggested that all psychotherapies are equally effective and referred to this notion as the ‘Dodo bird verdict’. The phrase referred to a famous quote taken from Alice’s Adventures in Wonderland, when the Dodo declares “Everybody has won and all must have prizes”, implying that if psychotherapies produce similar outcomes they “all must have prizes”. In the 1970s, the role of common factors in therapy became a popular discussion and consequently this resulted in a surge of research studies which aimed to examine how they impacted on outcomes (Laska, Gurman, & Wampold, 2014).

Evidence published mainly from comparative treatment studies suggest that diverse psychological therapies produce largely equivalent results (Laska et al., 2014; Lubrosky et al., 2002; Wampold et al., 1997). Studies investigating which variables are accountable for the most variance in therapeutic outcomes show that in addition to the client-therapist relationship (Flückiger, Del Re, Wampold, & Horvath, 2018; Wampold, 2001), client’s expectations of therapy also correlate with improved outcomes (Greenberg, Constantino, & Bruce, 2006). Lambert (1992) conducted one of the first meta-analyses of correlational studies in the area of common factors research. To provide a clearer understanding of the sources of variation in therapeutic outcomes, the authors categorised common factors, which are illustrated in Figure 7. The analysis showed that ‘common techniques’ accounted for almost a third of improvement in outcomes.

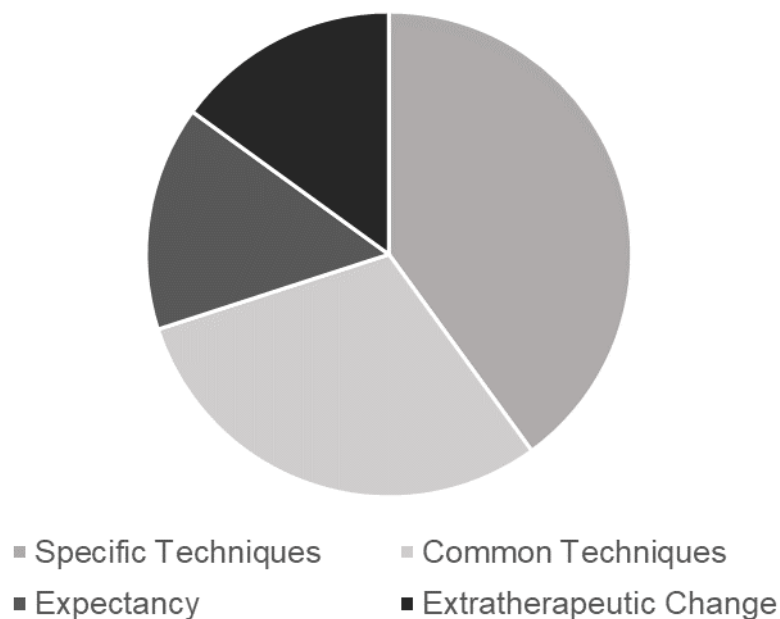


Figure 7. Factors contributing to the effectiveness of psychotherapy (Lambert, 1992)

A recent factor analysis by Tschacher, Junghan and Pfammatter (2014) of 22 common factors identified in the literature found that patient engagement, affective experiencing and the therapeutic alliance were judged most relevant in the therapeutic process. Despite variation in how common factors are used and categorised, correlational studies consistently report the working alliance as an important variable when predicting the effectiveness of interventions. Relationship factors, such as goal agreement, collaboration, empathy and positive regard are proposed to improve the outcome of therapy (Hatcher & Gillaspy, 2006). This suggests that there will be differences between therapists (i.e., some might be more skilful at developing an alliance than others and therefore will produce more effective outcomes). Multilevel analyses have shown that the therapists' contributions to the alliance are key in predicting outcome in comparison to the clients' (Baldwin, Wampold, & Imel, 2007).

Despite persuasive evidence to support the role of common factors in psychotherapies, the findings have been criticised for being misrepresentative due to averaging outcomes across primary and secondary outcome measures

(Crits-Christoph, 1997). Also, Beutler (2002) critiqued the common factors model and cautioned against assuming client and therapist homogeneity. Laska et al. (2014) highlight that there are several misunderstandings about common factors, one being that merely the therapeutic relationship is sufficient for change. To clarify, research has shown a relationship between an improved alliance and outcomes (Flückiger et al., 2018; Horvath, Del Re, Flückiger, & Symonds, 2011) but the alliance is only one factor that is necessary from the common factors model. The debate surrounding which factors are responsible for change in therapy is very complex and studies have questioned whether it is possible to dichotomise common and specific factors (Tschacher et al., 2014).

1.8 Specific Factors and Empirically Supported Treatments (ESTs)

Specific factors focus on technical components of the treatment model being used. The literature has suggested that specific factors are not critical to improve outcomes in therapy but the development of practice guidelines and Empirically Supported Treatments (ESTs) suggests otherwise (Chambless & Ollendick, 2001).

The literature suggests that some specific models and techniques show superior outcomes (Mayo-Wilson et al., 2014; Siev, Huppert, & Chambless, 2009; Tolin, 2010). Evidence has suggested superiority of particular treatments, including CBT for depression (Tolin, 2010), although some therapeutic models may be better suited to controlled evaluations and therefore have an advantage in producing positive results. For example, CBT is considered more structured in comparison to less explicitly directive therapies, such as, psychodynamic therapy, making it easier to measure and consequently might possibly skew the outcomes literature favourably to CBT.

Research has shown minimal evidence to support the utility of formulation as an intervention or a clinical tool in its own right. For example, if formulation was not used in therapy, would this have any effect on outcomes? Although this was not explicitly measured in this study (i.e., no participants received an intervention without a formulation), it is an interesting question to

hold in mind when interpreting findings and attempting to disentangle non-specific and specific factors that occur during therapy.

1.9 Development of the Concept of Alliance

The therapeutic alliance is one of the most intensely researched concepts in psychotherapy research (Castonguay, Constantino, & Holtforth, 2006). The term therapeutic alliance refers to a number of interpersonal processes which occur between the client and therapist (Elvins & Green, 2008) and is thought to act in parallel to the implementation of specific treatment techniques (Green, 2006). The concept of the alliance can be traced back to Freud's (1913) writings, where he acknowledged the client's conscious attachment to the therapist. The work of Rogers (1965) further developed the concept of alliance and operationalised the working alliance as a conscious process, involving the collaboration between the client and therapist (Greenson, 1965). Orlinsky and Howard (1975) synthesised ideas proposed from previous research and suggested three dimensions of alliance: working alliance (investment of client and therapist in the process of therapy), empathic resonance and mutual affirmation.

Bordin (1979) further developed the alliance concept and proposed that the alliance is achieved through collaboration and involves three key processes; an agreement on therapeutic goals, a consensus on tasks which are undertaken during therapy and the bond between the client and therapist. Bordin's model of alliance offers a pan-theoretical framework which can be applied to different therapeutic modalities, although he argues that different therapies may place emphasis on different aspects of the alliance (Bordin, 1994). This suggests that therapists using different therapeutic models may wish to place more focus on particular components of the working alliance.

There is no generally agreed definition of the alliance, although this has enabled clinicians and researchers from diverse theoretical backgrounds to utilise the concept within their specific understanding of the therapeutic process (Horvath et al., 2011). However, the detriment to not having a uniform definition

of the alliance concept has meant that the development of research to inform the literature has been ambiguous and complex (Horvath et al., 2011).

In this study the rationale for using Bordin's conceptualisation of working alliance was that it fits CBT well (Andrusyna, Tang, DeRubeis, & Luborsky, 2001). Andrusyna et al. (2001) conducted an exploratory factor analysis of the working alliance (measured on the WAI) and CBT. The analysis showed that the goal and task components of the working alliance are not distinct concepts and both covary with CBT. For example, in CBT a client's goal might be to change their negative thoughts (goal) and this might be achieved using a thought challenge (task). Findings also showed that each component of the working alliance (bond, task and goal) fit closely with CBT (Andrusyna et al., 2001), which supports that establishing jointly agreed goals, discussing ways to achieve goals and the importance of genuine therapeutic bond are fundamental to CBT (Beck, Rush, Shaw, & Emery, 1979).

1.10 Working Alliance and Outcomes: Overview of Evidence

Research has shown that the alliance accounts for a greater proportion of the outcome than the specific model of therapy (Duncan, Miller, Wampold, & Hubble, 2010). Also, evidence has shown that the alliance is especially predictive of therapeutic outcomes when it is established early in treatment and has been identified as a predictor of client dropout (Constantino & Wilson, 2002). This provides valuable clinical implications and suggests that therapists should focus on developing an alliance within the first moments of therapy and working through ruptures as they occur (Castonguay et al., 2006). Although research has established a correlation between the working alliance and improved outcomes (i.e., symptom change), we do not yet have a clear understanding of how this occurs within therapy.

Researchers have made a considerable effort to investigate the importance of the alliance within psychotherapies. For example, a task force set up in 1999 (Division of Psychotherapy's Task Force on Empirically Supported Therapy Relationships) aimed to identify components of effective therapy relationships and to define methods of tailoring therapy to the individual

(Norcross, 2001; later updated Norcross, 2011). Constantino and Wilson (2002) investigated which client characteristics and behaviours correlate positively and negatively with the alliance. Findings showed that psychological mindedness and hope for change positively correlated and avoidance and interpersonal difficulties negatively correlated with the alliance. Studies have also examined therapist's characteristics which are conducive of a positive working alliance. A review of therapist attributes and associated techniques identified; warmth facilitated by the therapist's understanding, flexibility which occurs through exploration and confidence demonstrated by accurate interpretations correlated with an improved working alliance (Ackerman & Hilsenroth, 2003). Studies have shown correlational evidence between some of the variables discussed here and an improved alliance, although clarity on how these processes occur and a firmer understanding of how they mediate the alliance is lacking.

1.11 Psychological Formulation and Working Alliance

A challenge of measuring formulation within a naturalistic setting is the complexity of disentangling processes which occur during therapy. There is clear overlaps in the conceptualisation of psychological formulation and the working alliance. For example, formulation involves developing a collaborative understanding of an individual's difficulties, which may also overlap with or contribute to the bond component of the working alliance (as defined by Bordin, 1979). Additionally, drawing out a diagrammatic formulation during a session may also correspond with the task component of the working alliance. As discussed in Section 1.10, studies have shown therapist characteristics and techniques that are particularly conducive of developing an effective alliance (e.g., understanding, exploration, accurate interpretations), all of which conceptually share aspects of the formulation process. Taking this into account, it may not be feasible to separate the process of formulation in practice from the working alliance, which creates a significant challenge when drawing conclusions about which variables correlate with each other.

1.12 Clinical Relevance and Study Rationale

Although formulation is commonly used and a core skill that is central to clinical psychology training and practice, there is currently little evidence to support the utility of it. Literature reviews have highlighted a distinct gap in the evidence-base, which has been further reiterated by the BPS and DCP recommending the need for further research. Aside from formulation, the literature has emphasised the importance of common factors, identifying key ingredients that are necessary for an effective psychotherapeutic intervention. As part of this, research has established a correlational but not causal relationship between the working alliance and improved outcomes across psychotherapeutic models. Currently, little is understood about whether formulation impacts on the working alliance within CBT and the relationship between formulation, working alliance and other psychosocial outcomes.

Margison et al. (2000) advised that evidence for the effectiveness of therapeutic interventions, including formulation, should be developed from practice-based evidence along with evidence-based practice. Therefore measuring formulation within clinical practice draws on the scientist-practitioner model and is most generalisable to clinical practice. In the current economic context of the NHS, there is increasing pressure for clinical psychologists, along with other healthcare professionals to 'prove their worth' (i.e., demonstrate what is practiced is also efficacious). Furthermore, the drive to deliver empirically supported treatments may shape how funding is provided in healthcare; as funding may go to therapies that have been able to demonstrate an evidence-base (Winter, 2006). Using methodologies such as single-case designs, allows researchers or clinicians to investigate complex processes (such as those that occur in psychotherapy) in a scientific and systematic way.

1.13 Research Aims and Questions: Defining Impact

The primary aim of this study was to examine whether formulation impacts on working alliance. Impact will be defined as the interaction of one variable (formulation; process and product) with another variable (working alliance). To measure impact, the researcher will focus on changes in the working alliance

(i.e., improve, decline or remain stable) at points when formulations are delivered during the intervention (i.e., when the product formulations are delivered or there is an increased frequency of process formulations).

2. Extended Method

2.1 Epistemology

This study was designed, conducted and findings were interpreted from a critical realist position. Critical realism is a philosophical stance established in response to the debate between positivism/empiricism and interpretivist/relativism (Houston, 2001). Whilst a critical realist accepts that there is a reality to be tested, they remain critical of the reality observed, with the aim of developing a deeper understanding of the phenomena (McEvoy & Richards, 2006). Critical realists move away from purist positivist assumptions, which are said to rely on observations of facts (Bechtel, 2009), independent from the researcher's frame of reference (Pring, 2000).

Critical realism lends itself to using multiple methods and triangulation, recognising the strengths of both quantitative and qualitative approaches to obtain reliable results and investigate complex concepts (McEvoy & Richards, 2006). Although some researchers have argued that quantitative and qualitative research approaches cannot be appropriately combined, due to differing assumptions about reality (Teddlie & Tashakkori, 2003), critical realism opposes this. Critical realism allows for quantitative and qualitative approaches to be combined to explore individual experiences, whilst using formal measures of underlying processes (Liscomb, 2011). Critical realism is well suited for case study research as it enables the researcher to study any phenomena, with the aim of understanding the processes and mechanisms in psychological interventions.

Given the complexity and challenges of researching formulation, adopting the position of critical realism seems appropriate, as it allows the researcher to maintain a critical stance and investigate the research aims using a multi-dimensional approach. Using a mixed methods approach will develop a

more comprehensive understanding of the processes that occur when delivering formulation during therapy (Rogers & Nicolaas, 1998).

2.2 Rationale for Study Design and Critique of Single Case Design Approach

The BPS (2011) outline a number of conceptual and methodological challenges which must be carefully considered and planned for when researching formulation. Some of these include, defining formulation (i.e., 'process vs event') and also separating the effects of the formulation from other variables occurring during therapy. Margison et al. (2000) advised that evidence for the effectiveness of therapeutic interventions, including formulation, should be developed from practice-based evidence along with evidence-based practice.

Taking these challenges into account, single case designs (SCDs) are particularly helpful when answering research questions about mechanisms of therapeutic change and the effectiveness of interventions. These designs can provide rich data and enable the discipline to translate empirical approaches into naturalistic clinical settings (Nash, Borckardt, Abbasa & Gray, 2011). The American Psychological Association's (APA's) Division 12 Task Force on Promotion and Dissemination of Psychological Procedures (DIV 12) outline that single case designs allow for systematic manipulation of independent variables (IVs) which can fairly test effectiveness of psychological interventions. Despite the appealing characteristics of SCDs, their popularity has diminished due to the increased use of group methodologies in the last 50 years (Borckardt et al., 2008). Randomised Controlled Trials (RCTs) and large *N* experimental studies have increased in status, particularly in large organisations such as the NHS, which are aiming to deliver the most effective. Nevertheless, SCDs capability to track individual outcome measures across multiple time points means that it is particularly suited for addressing the aims of this study.

The A-B SCD used in this study shares similarities with Single Case Experimental Designs (SCEDs), as it involves systematic and repeated measurement of Dependant Variables (DVs; working alliance, depression,

wellbeing) and the Independent Variables (IVs; formulation (product and process) and CBT) are manipulated by the researcher. Typically causal relationships are investigated using an A-B-A design, which involves a non-treatment phase (baseline) (A), followed by an intervention phase (B) followed by another non-treatment phase where the intervention is withdrawn (A). Applying an A-B-A design to psychotherapeutic treatments can be difficult as treatment effects cannot be “unlearned” and it is therefore not possible to return to the non-treatment baseline phase. Additionally, such designs have ethical limitations as withdrawing an efficacious treatment could be deemed unethical (Rassafiani & Sahaf, 2010).

The multiple-baseline A-B design allows the researcher to investigate a causal relationship between variables, without removing the treatment (Rassafiani & Sahaf, 2010). A multiple-baseline design involves the introduction of the intervention phase (B) at different time points, across participants creating a staggered baseline (e.g., delivering the product formulation at different time points across participants). This enables the researcher to make stronger conclusions about treatment effectiveness, particularly if the same change is observed across multiple subjects. A limitation of the A-B-A design, a major drawback of multiple baseline A-B designs is that it excludes participants from receiving the intervention, for different lengths of time (Barger-Anderson, Domaracki, Kearny-Vakulick, & Kubina, 2004). As this study uses a clinical sample from an NHS setting, implementing a multiple-baseline presents significant ethical challenges and was therefore deemed unsuitable. Also, this study is primarily focussed on investigating the impact of formulation on working alliance and is therefore less interested in overall treatment effectiveness (i.e., effectiveness of CBT).

The repeated single case AB design used in this study was considered to be the most ethically sound and appropriate design to answer the research questions. In view of the methodological and conceptual challenges of researching formulation, using a repeated single case, naturalistic design has enabled the researcher to use a scientific methodology within clinical practice, increasing clinical relevance.

2.3 Justification for sample size

Consistent with the study design, a total number of five participants was deemed to be sufficient. The sample size was informed by guidance published by the What Works Clearinghouse (Kratochwill et al., 2010), which recommends a minimum of three replications for SCDs (at least three cases) to achieve sufficient data. Due to the small number of participants in SCDs, replication with the same subject and across multiple subjects improves external validity of the study (Morgan & Morgan, 2008). A sample size of five was considered reasonable within the time frame of the study and would also allow for replication of any effects measured. Initially recruiting seven participants allowed for attrition, which was considered likely given the complexity of the client group and the intensive nature of the study (eight week intervention and completion of weekly measures).

2.4 Participants

All participants who took part in the study reported symptoms of low mood and depression, although depression was not any participant's primary diagnosis. See Table 10 for participant's primary diagnoses.

Table 10

Participant's primary diagnoses

Participant Number	Pseudonym	Primary Diagnosis
1	Luke	First Episode Psychosis
2	Louise	Borderline Personality Disorder
3	Julie	Bipolar Disorder
4	Heather	Paranoid Schizophrenia
5	Amy	Borderline Personality Disorder

2.5 Inclusion Criteria

To ensure participant's suitability for the study, eligibility was assessed using inclusion and exclusion criteria. Criteria and the rationale are outlined in Table 11.

Table 11

Outline and Rationale for Inclusion Criteria

Inclusion Criteria	Rationale
Accessing the CMHT	Met the standard service protocol.
Between the ages of 18 and 65	Part of the standard service protocol.
Present with symptoms of depression.	To ensure that an evidence-based treatment (CBT) was provided.
Be able to give informed consent.	To ensure participant has the capacity to decide on their involvement.
Be able to understand and speak English.	To be able to engage with CBT delivered in English. As the study is measuring working alliance, using an interpreter was not deemed appropriate due to the addition of a confounding variable.

2.6 Overview, Rationale and Critique of Measures

An overview and critique of each measure is provided here, outlining a rationale for why it was chosen for this study.

2.6.1 Working Alliance Inventory- Short Form (WAI-SF).

There is considerable variability in the conceptualisation and terminology used for the working alliance, which has resulted in numerous published outcome measures accessible to researchers and clinicians. A recent meta-analysis (Horvath et al., 2011) found that in the 201 studies reviewed, over 30

different alliance measures had been used. Four “core measures” were used in two thirds of the studies, which included the: California Psychotherapy Alliance Scale (CALPAS), Helping Alliance Questionnaires (HAQ), Vanderbilt Psychotherapy Process Scale (VPPS) and WAI. Measures focus on different components of the alliance, which ultimately creates difficulties when comparing results across studies. Elvins and Green (2008) provide a diagrammatic illustration of the development of the working alliance concept and commonly used alliance measures.

The WAI is theoretically underpinned by Bordin’s (1979) conceptualisation of working alliance and therefore measures three key components of bond, task and goal. Horvath and Greenberg (1989) developed the 36-item WAI scales, which include both client and therapist versions. A 12-item short-form of the WAI was developed by Tracey and Kokotovic (1989), which examined the four highest loaded items from each of the three dimensions to develop the short-form measure. The WAI-SF comprises of 12 items rated on a 7 point scale (never = 1 to always = 7) and has demonstrated a high correlation with the full 36-item version (.95) (Hatcher & Gillaspay, 2006). (See Appendix A and B).

Although numerous alliance measures have been developed (Muran & Barber, 2010) the 36-item WAI is the most commonly used measure in research (Smits, Luyckx, Smits, Stinckens, & Claes, 2015). There is less published data on the psychometric properties of the short-form but studies so far have evidenced that the WAI-SF has high internal-consistency on the therapist (.91-.96) and client measure (.91-.92). Test-retest has not been calculated for the WAI-SF, however is good for the full 36 item version (.73; Martin, Garske, & Davis, 2000). Also, convergent validity with other commonly used measures is good; CALPAS (.80) and HAQ (.74).

In summary, the rationale for using the WAI-SF in this study was that it measured aspects of the working alliance which are consistent with Bordin’s (1979) conceptualisation. Also, the measure is widely used in psychotherapy literature and has demonstrated good reliability and validity. Using a short-form

version also allows for consideration of participant fatigue, which is particularly important in this study given that measures are administered weekly.

2.6.2 Patient Reported Outcomes Measurement Information System (PROMIS) Depression – Short Form Measure.

The Patient Reported Outcomes Measurement Information System (PROMIS) is an initiative developed by the National Institute of Health (NIH), which was designed to improve self-reported outcome measures. Applying models from Item Response Theory (IRT), PROMIS uses a rigorous multi-step, mixed methods approach to develop a range of health-related measures, which include mental, physical and social health (Cella et al., 2010). The approach to developing PROMIS measures involves an iterative process of literature searches, item pooling, the development of conceptual frameworks, qualitative assessment of items using focus groups, expert reviews, cognitive interviewing and quantitative evaluation of items (Pilkonis et al., 2011). Figure 8 illustrates a flowchart outlining the PROMIS measure methodology.

The PROMIS depression measure specifically focuses on affective and cognitive manifestations of depression (Schalet et al., 2016). PROMIS have developed several versions of the depression measure, which include the full 28-item measure and four short forms ranging from four to eight items (Versions, 4a, 6a, 8a and 8b). The 8b short form measure (version used for current study – see Appendix B), specifically focuses on representing the range of the state (depression) and this is represented in the item bank. This 8 item short form was used in the Diagnostic and Statistical Manual of Mental Disorders – 5 (DSM-5) field trials, where it demonstrated its feasibility as a robust measure (Narrow et al., 2013). The 8 item short form has demonstrated a high correlation (.96) with the full 28 item depression bank (Cella et al., 2010).

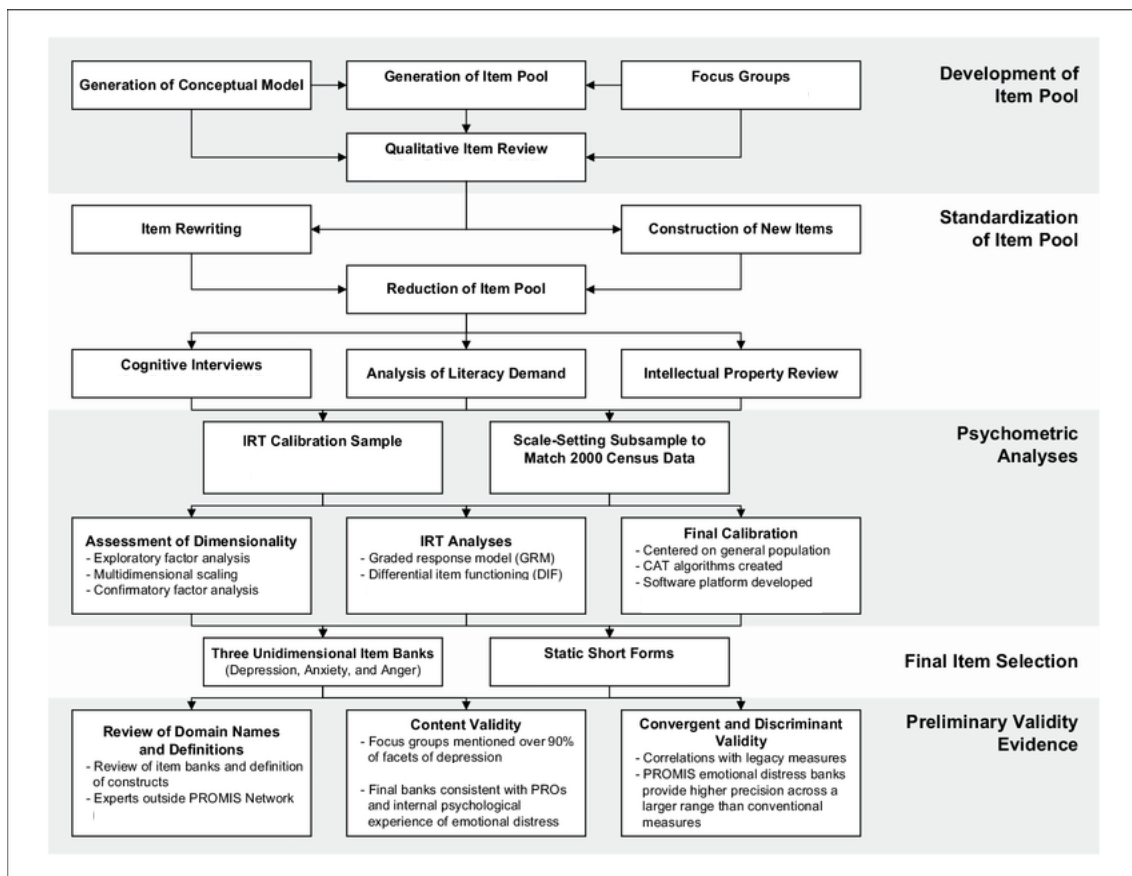


Figure 8: Flowchart of PROMIS methodology (Taken from, Pilkonis et al., 2011)

The 8-item short form shows strong convergent validity with other commonly used measures of depression, including, the Centre for Epidemiological studies depression scale (CED; .83) and the mood and anxiety symptom questionnaire (.72) (Cella et al., 2010). Less research has focussed on the psychometric properties of the short form version, however given the strong correlation between the 8 and 28-item version, consideration should also be given to these findings. The 28-item has shown strong convergent validity with the Patient Health Questionnaire - 9 ($r = .84$) and the Beck Depression Inventory -II ($r = .89$) (Choi, Schalet, Cook, & Cella, 2014).

Although other widely used measures of depression have good reliability and validity (e.g., BDI-II, PHQ-9) these are required to be administered every

two weeks and were therefore not appropriate for this study (i.e., measures administered following weekly therapy session). The PROMIS depression measure has demonstrated equally good internal consistency ($\alpha = .90$; (Vilagut et al., 2015) and convergent validity. Using a short-form version also considered the possibility of participant fatigue, which is particularly relevant as measures were administered weekly during the baseline phase and after therapy sessions.

2.6.3 Mental Health Continuum – Short Form (MHC-SF).

The MHC-SF measures subjective well-being across three subscales of emotional, psychological and social well-being (see Appendix C). The conceptualisation of well-being shifts away from understanding mental health using a medical model and focuses on the presence or absence of positive functioning (Keyes, 2002). Keyes (2005) highlights that the two-continua model of mental health states that wellbeing is linked with but is also different from mental illness. For example, an individual who has a diagnosis of depression is likely to experience a reduction in social functioning and life satisfaction, but this is not perfectly correlated.

The MHC-SF was developed by Keyes (2002) with the aim of developing a brief measure of subjective wellbeing. The short-form measure is 14-items long and was developed from a number of instruments measuring wellbeing used in the Survey on Midlife Development in the United States (Keyes, 2002). The subscales of wellbeing used in the MHC-SF are defined as;

- **Emotional Wellbeing:** refers to the presence or absence of positive feelings about life, evidenced by the presence of positive affect and perceived satisfaction with life.
- **Psychological Wellbeing:** refers to more personal and private criteria for evaluation of an individual's functioning in life.
- **Social Wellbeing:** refers to more public and social criteria in which an individual would evaluate their functioning in life.

The measure categories scores on the MHC-SF into the following (Keyes, 2002);

- **Languishing:** respondents are described as having an 'incomplete mental health' and report feelings of emptiness and stagnation in their life.
- **Flourishing:** respondents are described as 'flourishing' in life and have high levels of wellbeing, including positive emotions and are functioning well psychologically and socially.
- **Moderately Mentally Healthy:** respondents are considered to neither be languishing nor flourishing

The first evaluation of the MHC-SF was conducted with four communities in South Africa and showed good reliability and validity (Keyes et al., 2008). A further study conducted by Lamers et al. (2011) examined the psychometric properties of the MHC-SF in an adult Dutch sample and showed good test-retest reliability (.68). The MHC-SF also demonstrated good convergent validity with related outcome measures, including the Positive and Negative Affect Scale (PANAS) and Rosenberg Self-Esteem Scale (RSE) and good discriminant validity, showing a good fit with the two-continua model of mental health (Lamers et al., 2011).

The MHC-SF was used in this study as the conceptualisation of well-being is closely related to psychological formulation (i.e., understanding mental health with less focus on diagnostic labels and illness). Keyes (2002) understands wellbeing and mental health as closely linked concepts, but highlights that both do not always occur together (e.g., if someone has a diagnosis of a mental illness, this does not necessarily mean they are dissatisfied with life). Therefore measuring wellbeing is equally important to measuring symptoms of mental ill-health (e.g., symptoms of depression) as it reduces the risk of not capturing an individual's experience of distress. The MHC-SF is short in comparison to other measures of wellbeing and therefore considers participant fatigue, which is particularly relevant for this study.

2.6.4 Clinical Outcomes in Research Evaluation – Outcome Measure (CORE-OM).

The service where participants were recruited administered the CORE-OM (Evans et al., 2000) as a standard at pre and post interventions (See Appendix D). With consent from participants, the data from the CORE-OM was used for RCI and CSC analyses and pre and post intervention.

The CORE-OM has demonstrated good internal and test-retest reliability (Connell et al., 2007). The measure also shows good convergent validity and correlates with associated measures such as the Clinical Interview Schedule – Revised (CIS-R) and subscales with the BDI-II, Beck Anxiety Inventory (BAI), Brief Symptom Inventory (BSI) and Symptom Checklist – 90 (SCL-90) (Connell et al., 2007; Evans et al., 2002).

2.6.5 Cognitive Therapy Rating Scale (CTRS).

The Cognitive Therapy Rating Scale (CTRS; Young & Beck, 1980) (Appendix Q) is a tool developed to evaluate therapist's competence in cognitive therapy for depression (Beck et al., 1979). The scale is an observer-rated scale, which consists of 11 items across three subscales (general skills, interpersonal skills and specific cognitive therapy skills). Each item is rated on a seven point Likert scale and the CTRS manual provides behavioural descriptors to guide ratings.

The CTRS has demonstrated varied inter-rater reliability for single items, ranging from 0.54 (feedback) to 0.87 (application of cognitive-behavioural skills; Vallis, Shaw, & Dobson, 1986), although this is consistent with other psychotherapy rating scales (Lahey, Downey, & Saal, 1983). Although the CTRS is widely used in research and clinical practice, it has been critiqued for its lack of practical utility (Blackburn et al., 2001). Also, the scores on the CTRS do not differentiate well between different levels of therapist competence (Blackburn et al., 2001). The points on the scale are unclear, as only alternate points are defined, which results in varied degrees of interpretation from the

raters (Blackburn et al., 2001). Young and Beck (1988) superseded the original 11-item version (Young and Beck, 1980) with a 13-item version (Cognitive Therapy Scale – Revised, CTS-R). However, there are very few published studies using the CTS-R and more published research outlining the psychometric properties of the original CTRS, providing a rationale for using the CTRS in this study.

To ensure treatment fidelity, the CTRS was rated and recorded by the researcher whilst listening to audio recordings of therapy sessions. In addition to using the CTRS in supervision meetings, ratings were also seconded rated by the field supervisor for one full therapy session, for each participant (12% of sessions delivered). The literature suggests varied percentages for second coding, including 15% (David, Szentagotai, Lupu, & Cosman, 2008) and 20% (Westra, Arkowitz, & Dozois, 2009) of the full data set. Whilst it was important to ensure reliability of the data this was balanced with practicality (time pressures and availability of the second coder). Therefore, second coding 12% of the data, in addition to weekly supervision (where product and process formulations were discussed) was deemed sufficient.

Table 12 illustrates the frequency and time points of when measures were administered.

Table 12

Frequency and Time Points of Measures Administered

Measure	Time Point										
	B1	B2	B3	S1	S2	S3	S4	S5	S6	S7	S8
PROMIS Depression	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
WAI-SF Therapist				✓	✓	✓	✓	✓	✓	✓	✓
WAI-SF Client				✓	✓	✓	✓	✓	✓	✓	✓
MHC-SF				✓	✓	✓	✓	✓	✓	✓	✓
CORE-OM				✓							✓
CTRS				✓	✓	✓	✓	✓	✓	✓	✓

Note. B = Baseline. S = Session. ✓ = indicates measure was administered.

WAI-SF = Working Alliance Inventory – Short Form. MHC-SF = Mental Health Continuum – Short Form. CORE = Clinical Outcomes in Research Evaluation – Outcome Measure.

2.7 Rationale for Delivering ‘Product’ and ‘Process’ Formulations

Clearly defining formulation must be carefully considered when designing research studies (BPS, 2011). The BPS (2011) comment on the variation in which formulations are delivered during therapy and refer to this as ‘process vs event’. Practically, formulation may occur more commonly as a ‘process’, through a recurrent process of assessment, intervention, discussions, summaries and revisions between the client and therapist. In comparison, formulations that are presented diagrammatically or in written form, possibly occur less frequently in practice and understand formulation as a tangible process, e.g., as a ‘product’.

With this in mind, in this study, ‘formulations as a process’ have been referred to as ‘process formulations’ and ‘formulations as an event’ have been referred to as ‘product formulations’. In line with the theoretical concepts of CBT, it was agreed during discussions within the supervisory team that a process formulation would consist of three components, including an Antecedent (A), Belief/Cognition (B) and Consequence (C), which could be

delivered in any sequence, for example, A-C-B or A-B-C. An example of a process formulation may look like:

Therapist: I wonder whether when your husband talks to you like that (A), you feel sad and avoid speaking to him (C), because you think you are not good enough for him (B).

Therapist: When you are in physical pain (A), it seems that you think if I do not put a front on, then people will think you are an unfit mother (B) and that makes you feel very anxious (C).

Process formulations were delivered verbally by the therapist throughout the intervention, at points when they felt it was appropriate or beneficial for the participant. A product formulation was delivered twice during the intervention, during session three and seven. The product formulation was drawn out diagrammatically using the Beck (1995) longitudinal model (Appendix F).

2.8 Procedure

2.8.1 Ethical issues and ethical approval.

Ethical issues were considered and discussed within the research team prior to applying for and gaining ethical approval for the study. Ethical approval was granted from the East Midlands – Nottingham 1 Research Ethics Committee (Appendices H - K), the Health Research Authority (Appendix M) and the University of Lincoln ethics committee (Appendix M). The study obtained favourable opinion on 7th March 2017 and three further amendments were submitted and approved on 14th July 2017, 12th September 2017 and 26th February 2018.

2.8.1.1 Informed consent.

Using the eligibility criteria, Community Psychiatric Nurses (CPNs) identified potential participants on their caseloads and after giving them an overview of the study they gained verbal consent from participants for the researcher to contact them. The researcher then contacted potential participants via telephone and posted them an information sheet (Appendix O) and consent form and they were given one week to consider their participation

in the study. After one week, the researcher telephoned participants back to provide them with an opportunity to ask any questions, seek clarification on anything they wished and ensured that the participant understood what was required of them during the study, i.e. audio recording sessions and completing weekly measures. During the telephone call, the researcher arranged baseline measures and their first therapy appointment.

2.8.1.2 *Withdrawal from the study.*

At their request, participants were able to withdraw from the study at any point, including during and within two weeks of completion of the study. If participants wished for the data collected to be erased this would be done if requested within two weeks after the date of withdrawal. All participants were made of their rights to withdraw, without penalty and this information was detailed on the information sheet (Appendix O) and consent form (Appendix N). If a participant wished to withdraw from the study but not from the therapy they were receiving, the participant would have been able to continue with their therapy with no penalty, i.e. participants would continue with treatment as usual. Although it was felt that the risk of participants losing capacity during their participation was low, guidance was outlined from the outset in the event this occurred. If a participant lost capacity to consent during their participation, they were withdrawn from the study. Data already collected was retained and adhered to confidentiality and anonymity.

2.8.1.3 *Confidentiality and anonymity.*

The Confidentiality NHS Code of Practice (Department of Health, 2003) was followed to ensure that participant information was processed and managed fairly, lawfully and transparently. Confidentiality was clearly explained to all participants recruited in the study, including the parameters of confidentiality during therapy sessions. This included that the content of sessions would be discussed in supervision with the researcher's field supervisor (a member of the direct care team). Also, if a participant was to disclose information that raised concerns about their safety or the safety of others, this may be discussed with third parties if further action was required.

To protect participant's identity, all participants were given an individual participant number and pseudonym.

2.8.1.4 *Data storage and security.*

All digital recordings were transferred and saved onto an encrypted USB stick and erased from the audio recorder. Consent forms, which include full names and signatures of participants were kept in a locked filing cabinet on LPFT premises and then uploaded onto Silverlink (secure patient administration system). All contact details for participants were also kept on Silverlink and clinical notes following each therapy session were uploaded onto Silverlink and supervision records were stored in a locked filing cabinet or destroyed in confidential waste. All hard copies of the research data will be stored at the University of Lincoln and adhering to the university storage policy; data will be securely stored for seven years and then destroyed.

If participants give consent, anonymised data will be used for future research studies. However, if consent is not obtained, data will be destroyed as outlined above.

2.8.1.5 *Protection of research participants.*

As participants received psychological therapy, it was possible they may have found some topics of discussion distressing. As the researcher was the therapist and is also a Trainee Clinical Psychologist with substantial clinical experience, it was expected that they would be able to contain and manage any distress that occurred. If the researcher felt that the participant required further support or if the participant requested it, the researcher utilised supervision from the field supervisor and also considered appropriate referrals or signposting to further support, e.g. their CPN/key worker, crisis team.

2.8.1.6 *Debriefing of participants.*

At the end of therapy, all participants were debriefed by the researcher. Participants were provided with a debrief sheet, which gave them contact details for the researcher, research supervisors and other helpful organisations, e.g. the Samaritans. Participants were also given the opportunity to ask any

questions and were also offered the option to have a summary of the results from the study to be sent to them in the post.

2.8.1.7 *Risk for researcher.*

As the researcher was also the therapist, they received weekly supervision from the field supervisor. This ensured that the researcher had time to reflect on anything they wished and to also raise any concerns that they needed support with. In addition to providing support to the researcher, supervision ensured that the researcher delivered safe and effective practice to each participant. The researcher was also required to see one participant in their home (a standard service offered by the CMHT). The researcher ensured that she adhered to the Lincolnshire Partnership Foundation Trust lone working policy.

2.9 Recruitment Challenges

The researcher faced several challenges recruiting to the study, which required a substantial amendment to REC and a further research site was added. Initially the researcher intended to recruit from the adult psychology and psychotherapy service, although there were very few clients on the waiting list who had been recommended CBT following their initial assessment. Most service users on the waiting list had been recommended more lengthy (16 weeks) and alternative interventions, such as, CAT. With this in mind, it was agreed that the CMHTs may have more suitable service users for the study and an amendment was submitted to the relevant ethics committees. The researcher met with the CMHTs and service managers on several occasions to discuss the study and attended a couple of team meetings. Another CMHT was added as an additional research site in order to recruit a sufficient number of participants.

2.10 Baseline Phase: Stability and Number of Data Points

Until relatively recently, there were no published standards for single-case research, although several professional groups and task forces have since

proposed guidelines. The What Works Clearinghouse (WWC; Kratochwill et al., 2010) present the most detailed guidelines and standards.

The minimum number of data points in the baseline phase remains a disputed area of single-case research (Center, Skiba, & Casey, 1986; Huitema, 1985; Sharpley, 1987). In intervention research, researchers have suggested a typical baseline phase to range from 3 to 12 data points (Center et al., 1986; Sharpley, 1987). A review of 881 experiments suggested a modal number of three to four baseline data points (Huitema, 1985). However, longer baseline periods have been suggested to increase the validity of observations and reduce bias (Huitema & McKean, 1994). In conclusion, the WWC, DIV12 and DIV16 agree that a minimum number of three data points during the baseline phase is required. The literature also suggests the baseline must be relatively stable, free of significant trend and have marginal overlap with data in subsequent phases (Franklin, Allison, & Gorman, 1997). Visual analysis is most commonly used to assess the stability of the baseline (Smith, 2012).

As the current study uses a naturalistic design, waiting to achieve a stable baseline prior to introducing the intervention (IV) presented ethical challenges. As participants were recruited from the NHS it would have been unethical to wait until participant's baseline data stabilised (measure of depression), which would have required the researcher to delay access to the psychological intervention. Also, this study primarily focuses on the impact of formulation on working alliance and the relationship between formulation and psychosocial outcomes and is less interested in the impact of the CBT intervention on outcomes. To allow for a more accurate examination of whether working alliance and formulation impacted on depression, baseline data measuring depression was collected to determine the level and trend prior to intervention. With this in mind, based on the literature discussed and considering ethical implications, the current study used three data points and all participants started the intervention after this time period, whether their baseline data was stable or not.

2.11 CBT Intervention

The CBT intervention was informed by Beck et al. (1979) and primarily focussed on participant's experiences of low mood. In addition to the assessment and formulation, cognitive (e.g., cognitive restructuring) and behavioural (e.g., behavioural activation) techniques were used with the aim to improve participant's mood. National Institute of Health and Care Excellence (2009) recommend 16-20 sessions of a high intensity psychological therapy, such as CBT for adults with moderate to severe depression, which means that the intervention delivered in this study was outside of NICE guidance. However, this study was undertaken as part of a doctoral thesis and therefore time constraints limited the researcher's capacity to deliver a longer intervention.

2.12 Managing Dual Role as Researcher and Therapist

As already mentioned in the journal article, the researcher had a dual role in the study and she was also the therapist. There were several reasons for this and procedures were implemented to ensure the dual role was managed carefully.

Research has shown that formulation has poor inter-reliability (Flinn et al., 2015), therefore having one therapist, with a dual role of both researcher and therapist aimed to improve reliability of formulations delivered across participants. Also, it was expected that recruiting therapists from the CMHT service to undertake the research would have resulted in recruitment difficulties due to high workloads and a lack of resources within the service. It was therefore felt that the researcher conducting the therapy would be most appropriate.

However, the literature highlights the importance of considering researcher allegiance, referred to as the researcher's "belief in the superiority of a treatment...the superior validity of the theory of change that it associated with the treatment" (Leykin & DeRubeis, 2009, pp. 55). Researcher allegiance is an important factor to consider in this study and although the researcher took

significant steps to reducing the threat this may have had to the reliability and validity of the study, it is impossible to eliminate this entirely. Although studies that use a naturalistic methodology may be more prone to researcher allegiance, empirical evidence shows that methodologies such as gold standard RCTs are not entirely immune from bias (Kaptchuk, 2001). Furthermore, it has been highlighted that researcher allegiance may be an accurate reflection of true differences that occur during psychotherapy interventions, which are gained through intensive researcher and clinical involvement (Munder, Brüttsch, Leonhart, Gerger, & Barth, 2013). Although this hypothesis might make theoretical sense, there is little empirical evidence to support it, therefore researcher allegiance and how it is managed must be considered, particularly in psychotherapeutic research (Munder, Gerger, Trelle, & Barth, 2011).

The researcher received 90 minutes of weekly supervision, which involved listening to audio recordings of therapy sessions and using the CTRS to ensure fidelity to the CBT model. The researcher also kept reflective supervision notes following therapy sessions and did not look at participant ratings on outcome measures until the study had ended.

2.13 Second Coding Process Formulations

The frequency of process formulations were coded for each session and each participant by the researcher. In addition to listening to audio recordings during supervision, one full session for each participant was coded by a second rater (supervisor). Sessions were randomly selected using an online number generator. Once second coded, any discrepancies were discussed and if required sections of audio recordings were listened back to, so that a decision could be made as to whether criteria had been met for a process formulation to be coded.

2.14 Extended Analysis

Additional detail of the analyses used have been provided here. Also, the rationale for not undertaking further analyses of the effects of the intervention (CBT) are also outlined.

2.14.1 Visual Analysis.

Visual analysis is the hallmark method of interpreting intervention effects in SCDs (Lane & Gast, 2014; Smith, 2012) and is considered to be a reliable method (Baer, 1977). There have been several attempts to clearly define how visual analysis should be conducted (Smith, 2012) and researchers are advised to assess trend, level, variability, patterns of data points across phases (Kratochwill et al., 2010). Visual analysis has been criticised for being highly subjective and susceptible to individual interpretation and consequently error (Furlong & Wampold, 1982). When intervention effects are subtle, this reduces the reliability of visual analysis as there is often disagreement between judges (Lenz, 2013).

Visual inspection can be improved by using trendlines, which can show moment-to-moment changes of DVs alongside the IVs (Morgan & Morgan, 2008). Also, a trendline of the baseline phase can be superimposed over the intervention phase, to evaluate how the intervention data points deviate from this line. Other common analyses used in SCDs include the percentage of non-overlapping data statistic (PND), dual-criteria (DC) analyses and statistical process charts.

In this study, visual analysis was the main method used on graphical displays, focusing on trend, variability and patterns of data points at significant points in the intervention. No further analyses were undertaken to analyse the effect size of the intervention (CBT) as this was not an aim of the study. Although undertaking further analyses (such as, PND or DC analyses) may have calculated the effect size of the intervention, this extends to a different research aim (i.e. examining the effectiveness of CBT) and was therefore not

deemed appropriate. Trend lines were used to aid the visual analysis rather than examining the number of data points that fell above or below the trend line.

2.14.2 Simulation Modelling Analysis (SMA).

To strengthen the visual analysis, SMA was undertaken to examine the relationships across variables (Borckardt et al., 2008). SMA is a bootstrapping method which is used to analyse the correlation between two variables, adjusting for autocorrelation and reducing the risk of making Type I errors (the incorrect rejection of a null hypothesis). A series of observations (e.g., ratings of working alliance) is thought to be autocorrelated if the value of one observation depends on the value of the immediately preceding observations (e.g., frequency of process formulations) (Nash et al., 2011). That is, SMA examines non-concurrent or lagged relationships between variables across the course of therapy (i.e, does change in one variable (frequency of process formulations) precede change in another variable (working alliance)) from lag -1 to lag +1. A positive lag suggests change in variable one (e.g., frequency of process formulations) precedes change in variable two (e.g. working alliance ratings), whereas a negative lag suggests change in variable two (e.g., working alliance ratings) precedes change in variable one (frequency of process formulations). Results are reported as an R statistic which can be understood as a correlation, although it specifies temporal precedence (Borckardt et al., 2008).

In this study, SMA examined temporal relationships between the following pairs of variables, over the course of the intervention:

- Frequency of process formulations and working alliance (participant and therapist).
- Participant working alliance and therapist working alliance.
- Frequency of process formulations and depression.
- Frequency of process formulations well-being.
- Participant working alliance and depression.
- Participant working alliance wellbeing.

2.14.3 Determining Reliable and Significant Change.

Measurement is not always reliable and the difference between two scores, e.g. pre and post scores, could be due to measurement error (Morley, 2018). Jacobson and Truax (1991) suggest two methods to evaluate change in psychological treatments, in order to answer the following: 1) is the change reliable (Reliable Change Index; RCI) and 2) is the change clinically significant (Clinically Significant Change; CSC). RCI and CSC criteria were used when assessing outcomes at important points of the intervention (e.g., when the product formulation was delivered). If a measure had pre-established values for determining RC and CSC, these were used. For measures that did not, the following calculations were used.

2.14.3.1 *Reliable Change Index (RCI).*

Jacobson used classical test theory to determine confidence intervals around the pre-treatment score, which is referred to as the Reliable Change Index (RCI). The value of ± 1.96 was set to compare the RCI value, which is equivalent to the 95% confidence interval around the pre-treatment score.

To calculate the RCI value, the individual's pre-treatment score is subtracted from the post-treatment score and then divided by the standard error of the difference (SE_{diff}). The SE_{diff} is calculated using the Standard Error of Measurement of the test used. These calculations are outlined below:

$$RCI = \frac{\text{pre-treatment score} - \text{post-treatment score}}{SE_{diff}}$$

Figure 9. RCI Calculation

To calculate the SE_{diff} , the Standard Error of Measurement (SEM) is required for the following calculation (Figure 10).

$$SE_{diff} = \sqrt{2 \times SEM^2}$$

Figure 10: Standard Error of the Difference Calculation

The SEM is calculated by multiplying the Standard Deviation (SD) by the square root of 1 minus the coefficient reliability (r) (Figure 11). The coefficient reliability used in this study was the Internal Consistency (IC). The rationale for choosing the IC is that firstly, it is nearest to the conceptual basis for reliability and secondly, the SEM is smaller than the test-retest reliability and will therefore give a tighter estimate of the RCI (Morley, 2018).

$$SEM = SD \times \sqrt{(1 - r)}$$

Figure 11: Standard Error of Measurement Calculation

Once the RCI value has been calculated, one can determine whether the difference between the pre and post scores is reliable or not. If the value of the RCI exceeded 1.96, the change measured was deemed 'reliable change' at 95% confidence and is not due to measurement error.

2.14.3.2 Clinically Significant Change (CSC).

To determine whether RC is clinically significant, Jacobson and Truax (1991) proposed three statistically derived criteria; criterion a, b and c, outlined in Table 13 and cut-off points illustrated in Figure 12.

Table 13.

Definition of Criterion

Criterion	Definition	When to Use
Criterion a	Participant's post-treatment score falls <i>more than</i> two standard deviations from the mean of the clinical group, in the direction of the non-clinical group.	If normative data for a non-clinical population is not available.
Criterion b	Participant's post-treatment score falls <i>within</i> two standard deviations of the mean of the non-clinical group.	If the normative data for a non-clinical and clinical populations are available and the scores from both populations do not overlap.
Criterion c	Participant's post-treatment score falls closer to the mean of the non-clinical group than the clinical group.	If the normative data for a non-clinical and clinical populations are available and the scores from both populations overlap.

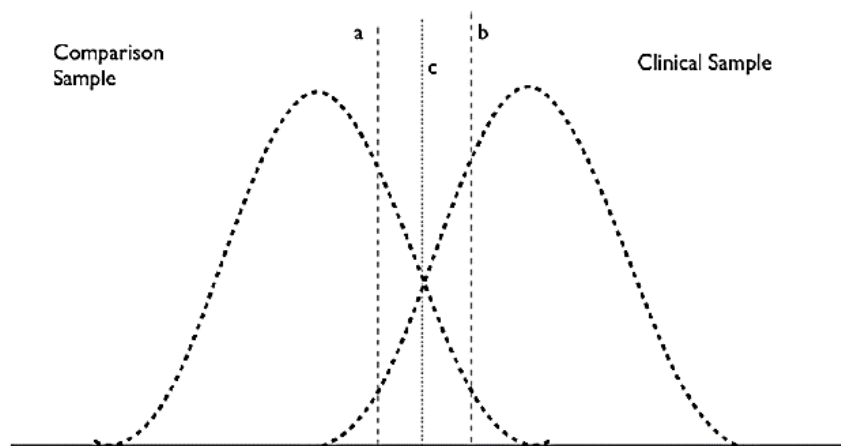


Figure 12. Illustration of the three cut points for criterion a, b and c (Jacobson & Truax, 1991).

3. Extended Results

The journal paper provides an overview of the key findings of this study and additional information is provided here; such as, supplementary participant demographics, T-score transformation, rationale for the norms used for the RCI and CSC calculations. Also sections of the extended results provide additional data and show calculations/workings out, therefore there are occasions where the extended results does not follow the narrative of the journal paper. The extended results have not been presented according to the research questions, however, where relevant this is highlighted for the reader.

3.1 Participant Demographics

Table 14 presents demographic information for the five participants who completed the study. Ages ranged from 35 to 60 (mean age 44.8 years), one participant was employed, one retired and three were unemployed.

Table 14

Participant demographics

Participant Number	Pseudonym	Age	Marital Status	Occupation
1	Luke	38	Divorced	Employed
2	Louise	35	Married	Unemployed
3	Julie	60	Married	Retired
4	Heather	52	Married	Unemployed
5	Amy	39	Separated	Unemployed

3.2 Participants Who Did Not Complete

Two additional participants began the study, although withdrew after session two. For the purpose of discussion here, they will be referred to as P6 and P7. During the first two sessions with P6, it was apparent that she was very unwell and concerns were raised with regards to risk to herself and others. It was agreed with her care team that P6 would be withdrawn from the study as it was unclear whether she had the capacity to consent for the study. P7 also withdrew after two sessions, as she was offered a different psychological intervention that was more appropriate to her treatment needs. It was agreed with P7 that it would not be feasible or beneficial for her to undertake two pieces of psychological therapy in parallel, therefore she decided to withdraw from the study. Due to the small amount of data collected, which had mainly focussed on the assessment, it was agreed amongst the supervisory team to not report the data in either the journal or extended paper. As seven participants were recruited for the study, this allowed for the attrition and meant that the recommendation for a minimum of three replications took place (Kratochwill et al., 2010).

3.3 PROMIS Depression T-Score Transformation

This study has followed guidance from the PROMIS depression scoring manual which advises users to translate raw scores into a T-score for each participant. The T-score rescales the raw score into a standardised score, with a mean of 50 and a SD of 10 (i.e., a participant with a T-score of 60 is one SD above the mean).

3.4 Means, Standard Deviations and Totals of Measures and Process Formulations

Table 15 outlines the means and standard deviations for each participant, on each measure and the total and mean frequency of process formulations delivered with each participant.

Table 15

Means, Standard Deviations and Totals for all Measures and Frequency of Process Formulations

Participant	PROMIS Depression Baseline <i>M (SD)</i>	PROMIS Depression Intervention <i>M (SD)</i>	Working Alliance Inventory Participant <i>M (SD)</i>	Working Alliance Inventory Therapist <i>M (SD)</i>	Mental Health Continuum <i>M (SD)</i>	Process Formulation Frequency Total (<i>M</i>)
P1	64.47 (2.07)	64.75 (4.09)	80.5 (3.24)	62.13 (7.08)	1.23 (.58)	45 (5.63)
P2	67.77 (3.45)	60.46 (4.51)	60.44 (4.55)	59.22 (10.13)	1.40 (.59)	29 (3.22)*
P3	72.57 (2.35)	71.63 (2.55)	78.5 (2.5)	57.38 (6.12)	1.22 (.27)	21 (2.63)
P4	65.77 (2.97)	61.91 (4.23)	53.75 (5.61)	52.75 (6.98)	1.46 (.46)	29 (3.63)
P5	76.77 (.27)	78.33 (2.46)	80.86 (4.19)**	51.38 (6.48)	0.42 (.22)	32 (4)

Note. *M* = Mean. *SD* = Standard Deviation. * P2 had 9 sessions. ** Missing data point. PROMIS Depression – higher scores indicate higher levels of depression. Working Alliance Inventory – higher scores indicate a stronger working alliance. Mental Health Continuum – higher scores indicate

3.5 Simulation Modelling Analysis (SMA) for Research Question One

SMA was undertaken to analyse the temporal relationship, between participant and therapist working alliance ratings and the frequency of process formulations. Table 16 provides correlational data, reporting whether the correlation is statistically significant, the direction of the association (+ or -) and at what lag the association occurred..

Table 16.

SMA Correlation Coefficients for Frequency of Process Formulations and Working Alliance

Participant	Lag	Process Formulations and Participant Alliance	Lag	Process Formulations and Therapist Alliance
1	+1	$r = -.13$	+1	$r = -.44$
	0	$r = -.48$	0	$r = -.24$
	-1	$r = -.58$	-1	$r = -.34$
2	+1	$r = +.29$	+1	$r = -.12$
	0	$r = -.04$	0	$r = -.02$
	-1	$r = -.51$	-1	$r = -.42$
3	+1	$r = -.40$	+1	$r = -.41$
	0	$r = -.21$	0	$r = -.04$
	-1	$r = +.77^*$	-1	$r = -.35$
4	+1	$r = +.26$	+1	$r = +.34$
	0	$r = +.46$	0	$r = +.02$
	-1	$r = -.24$	-1	$r = -.18$
5	+1	$r = -.02$	+1	$r = +.44$
	0	$r = +.13$	0	$r = +.56$
	-1	$r = +.79^*$	-1	$r = +.44$

Note. * = $p < .05$. + or – indicates direction of correlation (positive or negative).

3.6 Simulation Modelling Analysis (SMA) for Research Question Two

SMA was also undertaken to analyse the temporal relationship, between the frequency of process formulations, participant reported working alliance, depression and wellbeing (measured on the MHC-SF). Table 17 provides correlational data for the frequency of process formulations, wellbeing and depression, reporting the direction of association (+ or -), whether the correlation is statistically significant and at what lag the association occurred.

Table 17.

SMA Correlation Coefficients for Frequency of Process Formulations, Wellbeing and Depression

Participant	Lag	Process Formulations and Wellbeing	Lag	Process Formulations and Depression
1	+1	$r = -.15$	+1	$r = +.81^*$
	0	$r = -.32$	0	$r = +.18$
	-1	$r = -.27$	-1	$r = -.13$
2	+1	$r = -.67^*$	+1	$r = -.07$
	0	$r = -.15$	0	$r = +.27$
	-1	$r = -.18$	-1	$r = +.19$
3	+1	$r = -.10$	+1	$r = +.26$
	0	$r = -.16$	0	$r = +.36$
	-1	$r = +.13$	-1	$r = +.47$
4	+1	$r = +.54$	+1	$r = -.15$
	0	$r = -.47$	0	$r = +.31$
	-1	$r = +.19$	-1	$r = +.17$
5	+1	$r = -.41$	+1	$r = +.15$
	0	$r = -.12$	0	$r = +.41$
	-1	$r = -.76^*$	-1	$r = +.38$

Note. * = $p < .05$. + or – indicates direction of correlation (positive or negative).

Table 18 provides correlational data between participants' reported working alliance and wellbeing, outlining the direction of association (+ or -), whether the correlation is statistically significant and at what lag the association occurred.

Table 18.

SMA Correlation Coefficients for Working Alliance and Wellbeing

Participant	Lag	Participant Alliance and Wellbeing
1	+1	$r = +.35$
	0	$r = -.06$
	-1	$r = -.48$
2	+1	$r = +.20$
	0	$r = +.34$
	-1	$r = -.06$
3	+1	$r = -.33$
	0	$r = -.02$
	-1	$r = -.62^*$
4	+1	$r = +.94^*$
	0	$r = +.16$
	-1	$r = +.25$
5	+1	$r = +.01$
	0	$r = -.73^*$
	-1	$r = -.06$

Note. * = $p < .05$. + or – indicates direction of correlation (positive or negative).

3.7 RCI and CSC Calculations.

As outlined in the extended method, the RCI value was calculated to measure RC on the PROMIS depression, MHC and CORE measures at key points of the intervention (i.e., when the first and second product formulations were delivered and at post-intervention). Table 19 provides clinical and non-clinical normative data used for RCI calculations.

Table 19.

Comparison Data for Outcome Measures

Measure	Sample	Population	N	Mean (SD)
PROMIS Depression	Clinical (Vilagut et al., 2015)	Spanish adults experiencing a Major Depressive Episode in the community and inpatient settings.	65	54.3 (not reported)
	Non-Clinical (Liu et al., 2010)	Adults from the USA general population, in the 2000 general USA census.	5239	50 (10)
MHC-SF	Clinical (Fledderus, Oude Voshaar, ten Klooster, & Bohlmeijer, 2012)	Dutch adults experiencing mild to moderate symptoms of depression and anxiety, living in the community.	362	2.13* (.76)
	Non-Clinical (Corey L. M. Keyes et al., 2012)	Adult college/university students from across the USA.	5689	3.39 (.76)
CORE-OM	Clinical (Connell et al., 2007)	Adults from primary care counselling, clinical psychology and psychotherapy services in secondary care and generic outpatient and community mental health services.	10,761	18.3 (7.1)
	Non-Clinical (Connell et al., 2007)	General UK population.	535	4.8 (4.3)

Note. * Due to inconsistency in scoring (items scored 0-6 rather than 0-5), the mean has been adjusted accordingly to enable consistent comparisons (original reported mean = 3.13). *N* = number. SD = standard deviation

3.7.1 PROMIS Depression.

The PROMIS depression measure is a standardised measure and outlines a mean score of 50 and SD of 10, which was used to calculate the RCI and CSC (Liu et al., 2010). Informed by Jacobson's method, Revicki and colleagues (2008) propose that if the participant's score moves more than 2 SDs away from the mean, clinical significance has been achieved (Criterion a).

3.7.2 MHC-SF.

Clinical normative data outlined in Table 17 was used to calculate the RCI. Change was deemed CSC if the participant's score was greater than the RCI value (outlined in Table 18) and moved category (e.g., languishing to moderately mentally healthy).

3.7.3 CORE-OM.

The CORE-OM has published standardised RCI and CSC values, which were used in this study. If a participant's score moves by + or – 5 points, this indicates reliable change. If a participant's score is ≤ 10 , this indicates CSC (Connell et al., 2007).

Table 20 provides RCI values, indicating whether RC was achieved by exceeding the value of 1.96. For example, if the RCI value (calculated using the formulae in Extended Method) exceeded 1.96, one can be 95% confident that reliable change has occurred.

Table 20.

RCI Values Used to Determine Reliable Change

Participant	Measure	Product Formulation Session 3	Product Formulation Session 7/8*	Post Session 8/9*
1	PROMIS Depression	-0.22	0.65	2.26 ^R
	MHC	-0.26	-2.37 ^R	-2.14 ^R
	CORE	-	-	-
2	PROMIS Depression	0.45	2.48 ^R	2.08 ^R
	MHC	0.95	-3.52 ^R	-5.16 ^R
	CORE	-	-	-
3	PROMIS Depression	-1.23	-0.47	0
	MHC	0	0.23	-0.49
	CORE	-	-	-
4	PROMIS Depression	2.28 ^R	1.07	2.71 ^R
	MHC	0.69	-1.41	-1.41
	CORE	-	-	-
5	PROMIS Depression	-0.69	-0.69	-1.41
	MHC	0.69	1.41	1.18
	CORE	-	-	-

Note. * P2, product formulations delivered in session 3 and 8 and duration of intervention was 9 sessions. ^R = indicates reliable change SEM calculated using clinical normative data (See Table 17). PROMIS Depression SEM = 3.16. MHC SEM = 0.21. CORE SEM = 2.13. CORE uses standardised value of + or – 5 points to indicate reliable change.

3.8 Overall Synthesis of Results

The results showed inconsistency across participants which meant that that little evidence was found to show that psychological formulation directly impacts working alliance. Visual analysis of data presented in graphs (Figure 4) showed slight peaks in working alliance (reported by the therapist) at the point the second product formulation was delivered for three participants (P1, P2 and P4), although this was not consistent with participant measures. Visual analysis showed a peak in participant's measure of working alliance for two participants (P3 and P5) at the point the first product formulation was delivered, although this was not repeated with other participants. SMA showed just two statistically significant correlations between participant reported working alliance and the frequency of process formulations at a lag of -1 (P3 and P5). This suggests that an improvement in participant working alliance rating preceded an increased frequency of process formulations delivered in the following session. However, this finding did not meet the minimum number of replications and therefore cannot be generalised. In the change interviews, all participants commented on the therapist's characteristic and approach which they identified as helpful and could be linked with the working alliance. However, although all participants spoke about the formulation process and working alliance separately, they did not make a connection between the two variables.

The results also showed inconsistent and therefore limited evidence to suggest a relationship between psychological formulation, working alliance and psychosocial outcomes. Visual analyses examining formulation, working alliance and depression (Figures 2 and 3) showed a minimal trend between the two variables. SMA found several statistically significant lagged correlations between variables, however none met minimum replication criteria, therefore limited conclusions could be made. SMA reported a statistically significant correlation with two participants (P2 and P4), showing an increase in participant reported working alliance preceded an improvement in depression in the following session. RCI and CSC analyses showed one participant's (P4) depression reliably improved when the first product formulation was delivered and another participant's (P2) depression reliably improved at the second product formulation. Two participant's (P1 and P2) wellbeing scores reliably

improve and met criteria for clinical significant when the second product formulation was delivered. In the change interviews the majority of participants reported improvements in their cognitions, behaviour and/or mood, although they did not make links between changes and the formulation or working alliance.

3.9 Summary of Results for each Participant

To capture the idiosyncrasies of each participant, the following section provides a narrative of the findings for each participant, making reference to analysis of the measures conducted and responses on the change interview (refer to journal paper for tabulated/graphed results). Using supervision notes and the therapist's reflective log, additional information about the participant's journey through therapy is provided, commenting on general observations of their engagement during therapy and also any external factors outside of therapy that may provide evidence for and against change.

3.9.1 Participant 1: Luke.

Visual analysis showed a generally increasing trend in alliance over the course of the intervention. In comparison to other participants, Luke received the highest number of process formulations by a large margin ($n = 45$) and he also reported the second highest average working alliance score ($M = 80.5$), although no significant correlations (including lagged correlations) were found between process formulations and alliance.

Luke's data showed a slightly improving trend in depression during baseline and an improving trend from session 4 during the intervention. Results showed that Luke improved across all secondary outcome measures at post intervention. His scores on the depression measure and CORE-OM reliably improved at the end of his final therapy session and scores on the MHC-SF reliably improved and were also clinically significant at post-intervention. Luke's reported scores on the MHC-SF showed a reliable and clinically significant improvement at the end of session 7, when the product formulation was

delivered for a second time. The SMA showed one significant correlation at a lag of +1 between the frequency of process formulations and a deterioration in Luke's depression, which indicates that an increase in process formulations delivered by the therapist preceded a deterioration in depression in the following session. No other significant correlations were found across other variables.

During the change interview, due to difficulties mentioned below, Luke was tearful and quite withdrawn throughout. Luke was the only participant who talked about the accuracy of the therapist's questions, which he alluded to him feeling understood. He was also the only participant who could not remember much detail about the product formulations but recalled the process formulations, describing that the process formulations were "what the therapy was all about". It is unclear from Luke's responses whether he fully understood what a process formulation was (from the definition provided by the interviewer), as later he talks about "challenging his thoughts" as a helpful aspect of the formulation which could also overlap with cognitive techniques used in the CBT formulation.

Prior to starting therapy, Luke had recently finalised a divorce from his ex-wife and throughout therapy he was living separately from his children. At the end of therapy and at the time of the change interview, Luke decided that he was going to return back home (abroad) away from his ex-wife and children. This had a significant impact for Luke, as the decision was understandably very difficult for him and resulted in him feeling very emotional.

Throughout the CBT, Luke engaged well with both cognitive and behavioural tasks. On occasions he found it difficult to understand some of the concepts of more cognitively focussed tasks, e.g., undertaking a thought challenge, although after further explanation was provided, this aided his understanding and engagement. Although in the change interview Luke reported that he found the behavioural homework tasks difficult, e.g., activity scheduling, he persisted with these throughout. In a couple of sessions, Luke brought some of his achievements with him to share, including positive photographs he had taken throughout the week.

During the product formulation sessions, Luke seemed to be attentive throughout and was actively involved drawing out the diagram. The first occasion the product formulation was shared, Luke became quite tearful when discussing his core beliefs. He made several changes to elements of the formulation which he disagreed with and these were explored collaboratively. When the product formulation was shared a second time, Luke made less changes and generally agreed with the contents. He also presented less emotional than when the formulation was shared on the initial occasion and the content seemed to make more sense to him, likely due to his improved understanding of cognitive and behavioural concepts.

3.9.2 Participant 2: Louise.

Visual analysis of the alliance showed a generally increasing trend throughout the intervention, although there was a noticeable dip in Louise's report of alliance at session six. During this session, Louise reported having a particularly difficult week and the session focussed on encouraging Louise to challenge her thoughts using factual evidence. SMA showed no significant correlations (including lagged correlations) between the frequency of process formulations and the working alliance.

Louise's depression scores showed an improving trend during baseline and continued throughout the intervention, with an observable improvement in depression at session five. During session five, Louise had reported having a positive week as she had felt that she had been able to cope with difficult circumstances. She had also completed homework tasks during the week prior to the session and shared some of these achievements with the therapist, which were positively reinforced. SMA showed a significant correlation between the frequency of process formulations and a deterioration in well-being scores at a lag of +1. This suggests that there was a statistically significant relationship between the frequency of process formulations delivered with Louise and a deterioration in her well-being in the following session. Additionally, the SMA showed a significant correlation between the working alliance and improved levels of depression and a lag of +1. This indicates that an increase in Louise's

ratings of working alliance preceded an improvement in reported levels of depression in the following session.

The data showed that at the point the second product formulation was delivered and maintained at the end of the final session, Louise's depression had reliably improved. Additionally, when the second product formulation was shared and at the end of the final session, Louise's well-being scores were deemed reliable and clinically significant and her scores on the CORE-OM had also reliably improved.

During the change interview, similarly to other participants, Louise talked about positive therapist characteristics when she was asked about helpful aspects of therapy. Although Louise had some ongoing difficult personal circumstances (expanded below) during the course of therapy, she reported no negative changes and commented on only positive changes. Louise was the only participant who shared that she felt "dubious" about the process formulations and was also the only participant who described thinking about the formulations in-between sessions. When discussing the product formulation, Louise reported that she did not want to take away the formulation, as she felt "she had got it out of her system", although she also described some negative emotional reactions to the formulation which might also explain her reluctance to want to take a copy home with her. Louise was also the only participant to comment that if the formulation (product) had been shared during every session of the intervention, it would not have had the same effect, although she does not explicitly state whether she means a positive or negative effect.

Throughout the intervention, Louise described a high demanding life at home as she was a stay at home mother of seven children, which often resulted in her feeling exhausted, isolated and she had little time for herself. During session seven, Louise disclosed a significant safeguarding concern during the session, which resulted in this being the focus of the session and the product formulation was not delivered. It was agreed with Louise that due to this, we would extend the intervention to nine sessions and deliver the product formulation in session eight. This safeguarding concern was ongoing for Louise throughout the last three sessions and also at the time of the change interview,

which was understandably very difficult for her although she commented on how surprised she was that she had coped as well as she did.

Throughout the CBT intervention Louise engaged well, particularly with in-session tasks such as, the continuum exercise, psychoeducation of cognitive-behavioural principles. When we shared the first product formulation, Louise was not tearful but it was clear from her observable presentation that she found the formulation difficult to process and she commented that she felt shocked seeing it written down. In the session Louise described a moment of realisation of what she had been through, which had mixed consequences of feeling shocked but also she reported that it helped her to make sense and normalise why she experiences depression.

3.9.3 Participant 3: Julie.

Julie was the only participant who showed a flat trend on participant reported alliance throughout the intervention. Additionally, the lowest frequency of process formulations were delivered with Julie ($n = 21$). Visual analysis showed a slight peak in the participant reported alliance when the second formulation was delivered, however this was not the only peak during the intervention. SMA showed a positive significant correlation between process formulations and participant reported alliance at a lag of -1, which means that an increase in Julie's working alliance ratings correlated with an increased frequency of process formulations delivered in the following session.

Julie was also the only participant who showed a worsening trend in depression scores during the baseline phase. SMA showed no significant correlations between process formulations and depression or wellbeing. Also, SMA showed no significant correlations between working alliance and depression, although a negative significant correlation was found between Julie's working alliance ratings and wellbeing at a lag of -1. This indicates that a deterioration in Julie's wellbeing preceded a change in Julie's ratings of the working alliance. Although depression scores improved at the point the first and second product formulations were delivered, these improvements were not deemed reliable. The data showed no improvement in Julie's depression at

post-intervention. Julie's scores on the MHC-SF generally remained the same when both product formulations were delivered and although there was an improvement in Julie's wellbeing at post-intervention, this was also not classified as reliable. Julie showed a reliable improvement on the CORE-OM at post-intervention.

Throughout the majority of the intervention, Julie had a lot of input from other professionals which included weekly visits from her peer support worker and CPN. During the last couple of weeks of therapy, her peer support worker was off work on sick leave and she had also not been seen by her CPN for several weeks. This became a focal point for the last couple of sessions with Julie as she was unhappy about the prospect of therapy ending and not having received as much professional involvement as she had previously in the intervention.

In the change interview, Julie talked about the therapist's characteristics as being helpful during her experiences of therapy. Julie was the only participant who shared that she did not always agree with the therapist's suggestions but implied that the positive alliance enabled these disagreements to be discussed. During the change interview Julie described that she felt shocked and thought "that's not very nice" when initially seeing her product formulation, however she did not share this with the therapist during the session but raised some disagreements in the following session.

Throughout the intervention Julie was very talkative and she would often dominate sessions and her conversation would veer off on tangents which were difficult to refocus. The therapist reflected that this resulted in less space for process formulations to be delivered and CBT tasks to be undertaken. Julie engaged relatively well with in-session tasks but less well with homework, particularly if she was required to do tasks independently. Julie's peer support worker would encourage her to participate with activities, e.g., badminton, going for walks or a coffee, which supported Julie with homework tasks that focused on behavioural activation principles.

During the first product formulation, Julie engaged very well and described that the content "made sense" and it provided her with information

that she had not considered previously. However, in the following session Julie raised that she had thought about the formulation between sessions and she disagreed with some of the contents.

3.9.4 Participant 4: Heather.

Data shows an increasing trend in working alliance throughout the intervention with a slight peak at the point of the second formulation, however this peak follows an increasing trajectory of working alliance throughout therapy. Heather reported the lowest average working alliance score ($M = 53.75$) which was also consistent with the therapist's measure of alliance, reporting the second lowest average score ($M = 52.75$). SMA showed no statistically significant correlations between the frequency of process formulations and working alliance.

Heather's depression scores showed an improving trend during the baseline phase and an improving trend from session four of the intervention. SMA showed no statistically significant correlations between the frequency of process formulations and depression or wellbeing. However, SMA did show a significant correlation between working alliance and wellbeing at a +1 lag, which suggests that an increase in working alliance correlated with an improvement in wellbeing in the following session. Additionally, SMA found a statistically significant correlation at a +1 lag between working alliance and depression, which indicates that an increase in Heather's working alliance ratings preceded an improvement in depression reported in the following session.

Heather's reported levels of depression reliably improved at the point the first product formulation was delivered, which further improved at post-intervention. Heather's well-being scores initially deteriorated when the first product formulation was delivered, but then improved following the second product formulation and at post-intervention, although these improvements were not deemed reliable. Heather's scores on the CORE-OM show a reliable improvement at post-intervention.

Heather declined to take part in the change interview, therefore there is no qualitative interview data to report.

Although the focus of the intervention was on Heather's low mood, her primary diagnosis was Paranoid Schizophrenia. Heather reported experiencing symptoms associated with her diagnosis of Schizophrenia, which included paranoid thoughts resulting in her feeling very anxious. During sessions, Heather's experiences of paranoia frequently impacted on her ability to engage with therapy, for example, she described feeling anxious about opening up during therapy due to her fear that something bad would happen to her or the therapist. As a result Heather was often reluctant to share any of her cognitions which created barriers when developing her product formulations or engaging in cognitive-behavioural techniques. From the therapist's perspective, due to Heather's paranoia it felt more difficult to develop a working alliance, particularly in such a short space of time (8 sessions).

3.9.5 Participant 5: Amy.

Similarly to other participants, the working alliance showed an increasing trend throughout the intervention, with a slight peak at the point the second formulation was delivered. Amy reported the highest average working alliance ($M = 80.86$) but the therapist scored the lowest average ($M = 51.38$). SMA showed a statistically significant correlation at a -1 lag between the frequency of process formulations and an increase in working alliance. This means a relationship was found between an increase in Amy's working alliance ratings and an increase in the frequency of process formulations delivered in the following session.

Amy was the only participant who showed stable depression scores throughout the baseline phase. During the intervention, Amy reported little variation in depression scores, although there was a slight improvement between sessions two and four. On average, Amy reported the highest (worse) depression score and the lowest (worse) wellbeing score during the intervention. SMA showed a statistically significant correlation between the frequency of process formulations and a deterioration in wellbeing scores at a lag of -1. This suggests that a deterioration in Amy's reported wellbeing preceded an increased frequency of process formulations delivered by the

therapist in the following session. SMA also found a significant negative correlation between working alliance and wellbeing (0 lag), which suggests a relationship between working alliance a deterioration in wellbeing at the end of the session delivered.

Amy's reported levels of depression deteriorated at the point the first product formulation was delivered, which remained stable at the second product formulation and then further deteriorated at post-intervention. Amy's wellbeing scores also deteriorated during the session the first product formulation was delivered, then further deteriorated when the second formulation was shared and slightly improved at the end of the final session but did not improve overall. Amy's ratings on the CORE-OM showed a slight improvement at post-intervention which was classified as a reliable change.

During the change interview, similarly to other participants Amy talked about the therapist's characteristics and approach which she found helpful. Amy was the only participant who made any reference to the therapy being challenging but commented that although it was sometimes difficult, she felt as though she needed it. Specifically to the product formulation, although Amy described it as overall a positive experience, it was difficult seeing the formulation written down, likening it to "confronting her demons". In addition to another participant, Amy also commented that she found the formulation made more sense the second time it was shared with her.

External to therapy, Amy had several ongoing stressful circumstances which she would often talk about during sessions. Amy had a diagnosis of Fibromyalgia and as a result she would often experience significant pain which she linked to her low mood and intolerance for others. During sessions, Amy would sometimes be in physical pain which would impact her ability to engage, e.g., sit comfortably for the duration of the session. Although Amy had ongoing stressful circumstances she had a lot of positive support from friends, which encouraged her to have an active social life. Also, Amy had a good relationship with her CPN who she was in contact with on a regular basis.

Throughout sessions, Amy was often very emotional and her mood would fluctuate from being quiet and withdrawn to tearful and also very angry

and frustrated. From the therapist's perspective, at times this was difficult to manage and on reflection this may have impacted the therapist's ability to develop a working alliance. Amy engaged relatively well with CBT, although she would often challenge some of the in-session tasks and she was reluctant to undertake any homework. When developing the product formulations, Amy was very tearful throughout, particularly during the first product formulation. Although Amy was very emotional, as previously commented, this was not unusual to her presentation during other sessions.

4. Extended Discussion

The extended discussion will further expand on ideas explored in the journal paper, making reference to psychological theory and existing research. Additionally, it will further discuss the implications of findings for the profession considering the study's limitations and recommendations for future research.

Psychological formulation is a core skill of clinical psychology practice and training and is considered a central component of the majority of psychological therapies (DCP, 2010). Despite the emphasis placed on the utility of psychological formulation, there is a limited evidence-base to suggest that it improves outcomes and the working alliance (Bieling & Kuyken, 2003). An overarching aim of this study was to contribute to the dearth of research examining whether CBT formulation impacts outcomes in therapy. In summary, the findings of this study found limited evidence to confirm whether formulation impacts working alliance and little or no relationship between formulation, working alliance and secondary outcomes (depression and wellbeing).

4.1 Does Formulation Impact Working Alliance?

Although the study found a slight trend between formulation and working alliance, the results were not able to confirm whether formulation directly impacts working alliance during therapy. Results showed little consistency and repetition across participants which meant that minimum replication criteria (three replications) was often not met, which limited the generalisability of

findings. The majority of participant's data showed an increasing trend in working alliance over the course of the intervention. This was further supported in the SMA, which showed a strong statistically significant correlation between participant and therapist reported working alliance (at lag 0), which was repeated with three participants. This does not offer a unique finding to the literature, but supports previous research that shows that although the alliance reported by therapists and clients typically follows a U-shaped curve (high-low-high), the alliance follows a steadily increases trend over the course of therapy (Gelso & Carter, 1994).

Visual analysis showed some elevations in working alliance at significant points in the intervention when product formulation/s were shared or when a higher frequency of process formulations were delivered. However participant and therapist reports of working alliance were not consistent, i.e., peaks did not occur at the same points, which suggests that the visual analysis did not find that formulation impacts working alliance. In addition to this, SMA found two statistically significant, positive correlations at a lag of -1, which suggests a slight relationship between an increase in working alliance (reported by the participant) and an increase in process formulations delivered by the therapist in the following session. Although this finding shows a slight relationship between these two variables and suggests that working alliance may have a lagged correlation with the frequency of process formulations delivered, this was not repeated across three subjects and is therefore limited. No studies have examined the relationship between CBT formulation and working alliance using SMA, therefore it is difficult to link this finding to pre-existing literature (Aston, 2009; Bieling & Kuyken, 2003). Research has shown that the accuracy of therapist's interpretations in psychodynamic therapy are positively correlated to an improvement in therapeutic alliance in proceeding sessions (Crits-Christoph, Barber, & Kurcias, 1993). Although this study suggests that the accuracy of formulations might act as a mediating factor of the working alliance, it is important to consider how accuracy is defined and measured. The current study did not measure the accuracy of formulations delivered, therefore it was not possible to further explore whether the accuracy of CBT formulations

mediated working alliance during therapy, potentially highlighting an area for future research.

Participant findings from the visual analysis were not consistent with therapist reported working alliance. The discrepancy between participant and therapist findings supports previous literature published by Chadwick and colleagues (2003), which found that although therapist's reported that formulation contributed to the therapeutic alliance and was a validating process for the client, this was not supported by participant's responses. This may indicate that the benefits of formulation may be for the therapist rather than the client. If so, this may have implications for the profession and raises the question whether formulation should be used as a clinical tool directly with clients or indirectly during supervision or independent study.

During the change interviews, all participants talked about therapist characteristics when asked about helpful aspects of the therapy. This finding supports previous research which has shown that clients often attribute positive experiences or outcomes of therapy to therapist's personal attributes (Sloane, Staples, Cristol, Yorkston, & Whipple, 1976). Participants in the current study described that the therapist had contributed to them feeling "understood", "comfortable", "never judged" and "listened to". These are consistent with previous findings from Ackerman and Hilsenroth's (2003) study, which demonstrated a positive correlation between similar therapist attributes and positive outcomes in therapy. Additionally, a study conducted by Lazarus (1971) found that clients reported that personal qualities of the therapist were more important than specific technical components of therapy, which supports the common factors model which proposes that common factors account for 30% of improvement in therapy outcomes (Lambert, 1992). Baldwin et al. (2007) suggested that the therapist's contribution to the development of the alliance is essential to producing improved outcomes. This may suggest that some therapists are more skilled at establishing more effective alliances than others. In the current study, the same therapist was used across participants, therefore we were unable to measure whether variation in therapists would mediate outcomes, including the working alliance.

In the change interview, participants commented on aspects of or positive changes associated with formulation and CBT, although they did not make specific links between them. For example, some participants commented on changes in their thoughts (e.g., “recognise and challenge my black and white thinking”), behaviours (increased levels of activity) and emotions (e.g., feel less guilty, more accepting, can process how I feel and let go of bad feelings quicker). Although a key goal in CBT is to alter cognitions and behaviours, with the aim of improving an individual’s emotional state, it cannot be entirely conclusive that these changes reported by participants were solely a result of CBT, the working alliance or formulation. However, it should be highlighted that participants did report improvements which are reflective of the CBT model. When asked about helpful aspects of the formulation, participants generally talked about feeling understood, for example, “seeing it all written down in a diagram, it made sense”, “when we drew it out, it helped me to get it”. Needleman (1999) proposed that if the formulation contributes to clients feeling understood by the therapist, this may indicate that formulation has a role in the development of the therapeutic alliance. Although Needleman’s idea makes logical sense, considering the findings from this study and existing research, there is little empirical evidence to support that if formulation contributes to these experiences for the client, this results in an improvement in the working alliance.

4.2 What is the Relationship between Formulation, Working Alliance and Psychosocial Outcomes?

The study showed mixed findings in the relationship between formulation working alliance and psychosocial outcomes measures. Although the majority of participants showed an improvement in depression, wellbeing and across a range of symptoms on the CORE, it is not possible to attribute these changes specifically to the formulation, CBT or working alliance.

SMA showed inconsistent correlations between the frequency of process formulations and psychosocial outcomes (depression and wellbeing), which suggests no relationship between formulation and outcomes. SMA also showed mixed results in the relationship between the working alliance,

wellbeing and depression. Although two statistically significant correlations were found between an improvement in working alliance and a reduction in levels of depression in the following session, although minimum replication criteria was not met. This supports existing literature which found that the working alliance is positively correlated with improved outcomes (Horvath et al., 2011), although the findings from this study cannot conclude any clear relationships between variables. Figure 13 illustrates statistically significant correlation coefficients found between variables, indicating the direction of the correlation (+ or -) and at which lag the association occurred (-1, 0 or +1 lag). This figure highlights the level of inconsistency and lack of repetition in relationships found between variables.

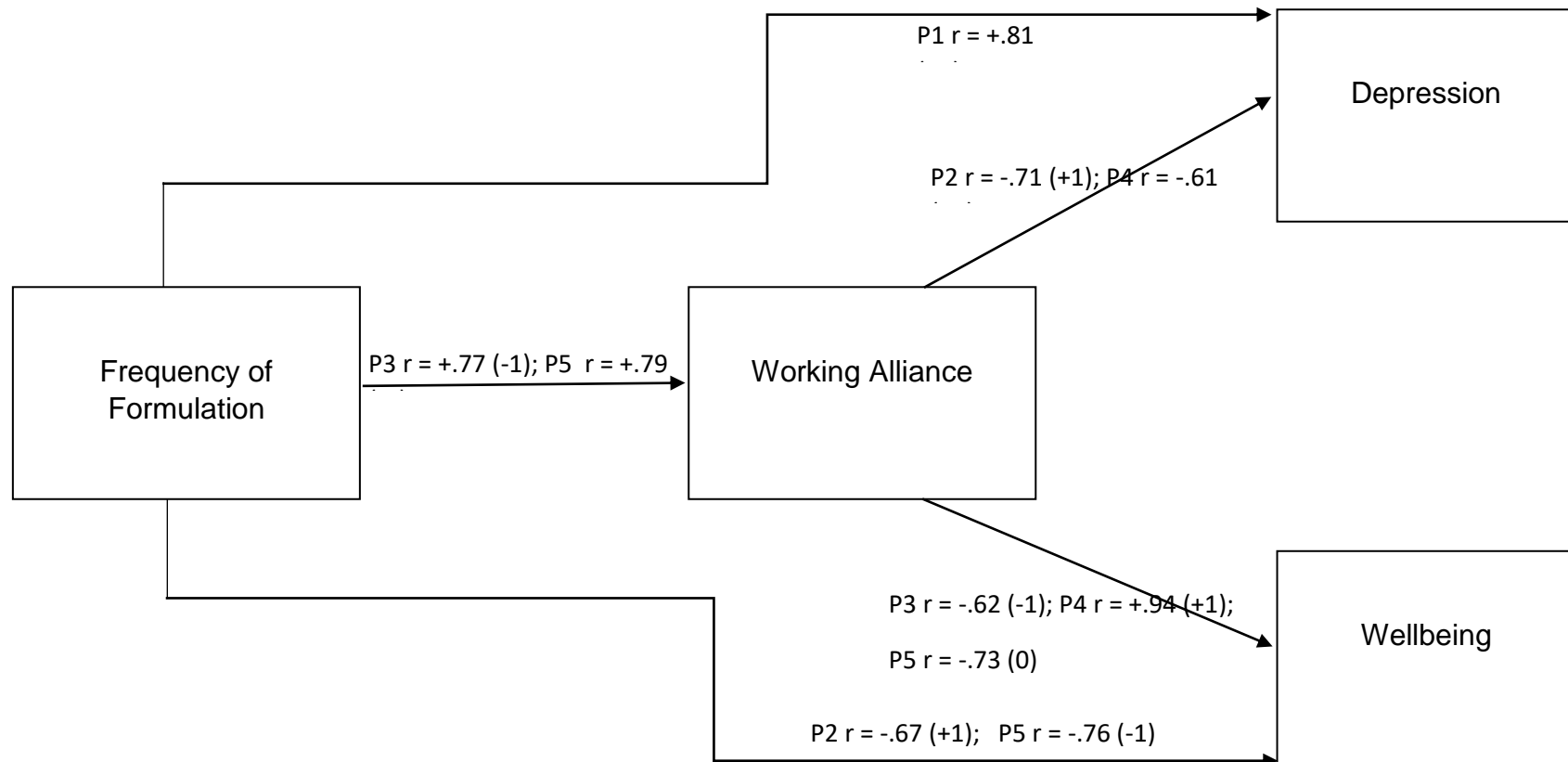


Figure 13. Statistically Significant Correlation Coefficients between Variables

Note. P = Participant; $p \leq .05$. + or – indicates direction of correlation (positive or negative)

Results showed some evidence to suggest that delivering a product formulation might be a distressing experience for clients. Data showed a deterioration in depression scores (for two participants) when the product formulation was delivered (See Table 6 – RCI and CSC). Also, during the change interviews three participants reported that receiving the product formulation resulted in negative emotional reactions, for example, “I felt a bit overwhelmed...seeing everything from my past, it was a shock”, “at first I thought ‘that’s not very nice’”, “it was hard to look at...it was like having to relive it again...like confronting a lot of your demons”. All participants who described a negative emotional reaction also commented that the product formulation had also been helpful in developing insight into their difficulties. This finding supports existing literature that whilst the majority of clients describe formulation as overall being a helpful tool in therapy, clients can also experience some level of distress when receiving a formulation (Kahlon et al., 2014; Redhead et al., 2015). In Brown (2008) unpublished doctoral thesis, grounded theory was used to develop a theoretical understanding and model of client and therapist’s experience of formulation (Figure 14). Brown highlights client’s experience of initial doubt, which progresses to an ‘awareness of the process’. She suggests that increased awareness resulted in client’s being more consciously aware of complex personal information, contributing to feeling frightened, exposed and overwhelmed adding to clients’ distress. Brown suggests that ultimately clients were able to move away from their initial doubt, through a process of increased awareness and associated distress to feeling the formulation encouraged a sense of empowerment. Although this model has not been published and the generalisability has not yet been tested, the qualitative findings of the current study offer some support to Brown’s model, as although some participants reported some level of distress when receiving the product formulation, overall they generally described the formulation as a positive and helpful experience.

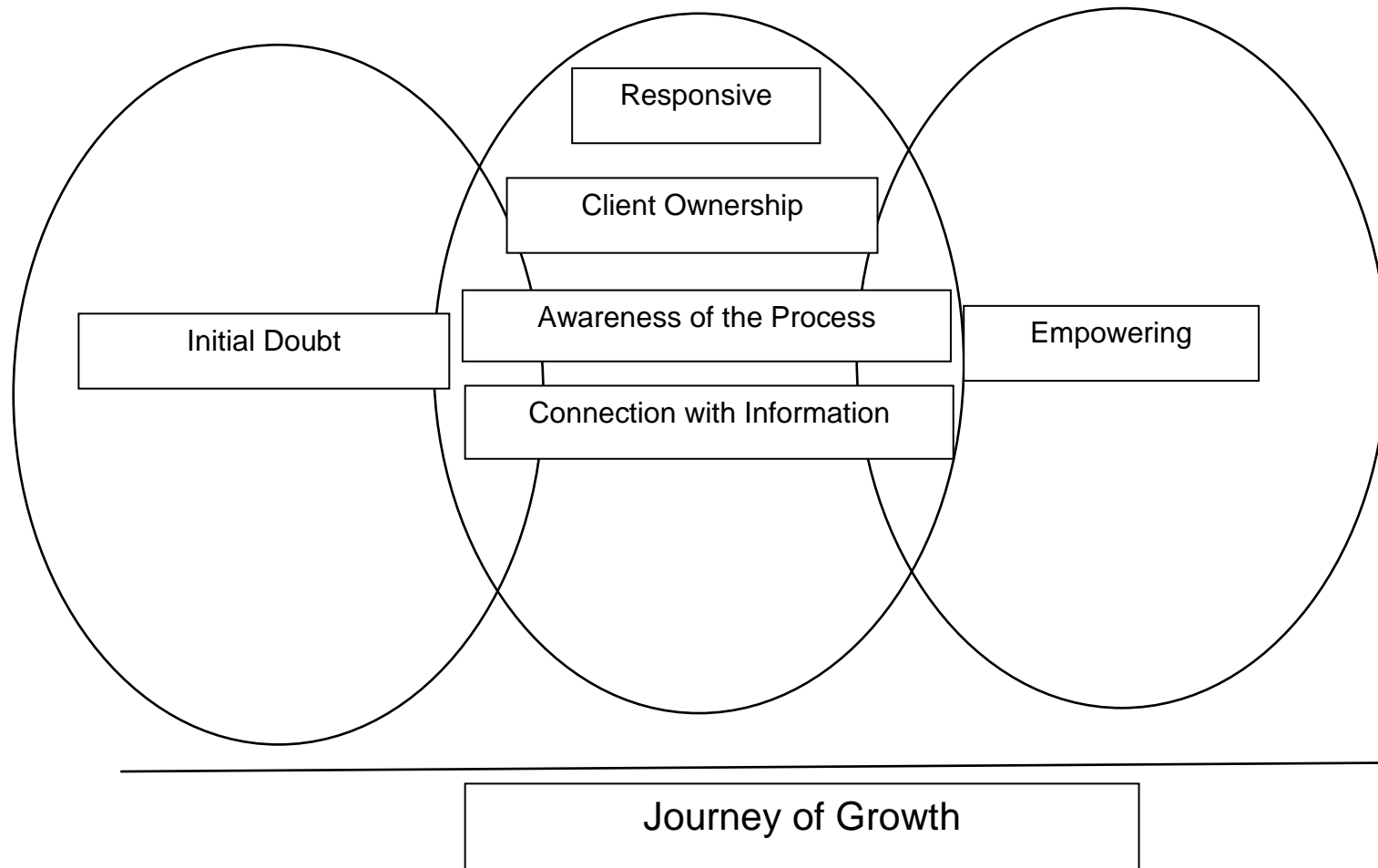


Figure 14. Theoretical Diagram – Clients' View of Clients' Experience of Formulation (taken from (Brown, 2008))

4.3 Limitations and Challenges

The limitations and challenges of the study have been referred to throughout the extended and journal discussion. The most significant challenge of this study was disentangling formulation from other processes occurring in therapy and will therefore be the main focus of this section.

4.3.1 Disentangling Formulation from Specific and Non-Specific Factors.

Separating the formulation out from other processes in therapy resulted in difficulties when attempting to conclude which variables contributed to which outcomes measured in therapy. There are clear overlaps in the conceptualisation of delivering a psychological formulation, components of CBT and establishing a working alliance, which must be considered when attempting to unravel such complex processes. As discussed in the journal paper, delivering a psychological formulation may contribute to or enact elements of the working alliance (e.g., bond) and the working alliance might also be difficult to separate from components of CBT (e.g. homework tasks, goal setting). Table 21 provides a visual representation of some of the potential overlap between these variables.

Table 21.

Visual Representation of the Overlap between Working Alliance, Psychological Formulation and CBT.

	Working Alliance		
	Task	Bond	Goal
Psychological Formulation	Delivering a formulation, e.g., drawing out diagrammatically.	Collaborative process. A shared understanding.	Informs intervention, guided by mutually agreed goals.
Cognitive Behavioural Therapy	In-session and homework tasks.	Collaborative therapy. An effective alliance is central to the therapy.	Setting and working towards measurable goals.

This overlap may have contributed to measurement difficulties, highlighting whether you can measure each process separately or are there occasions when you are measuring aspects of the same process. This is a potential challenge of psychotherapy research when measuring processes that occur within naturalistic settings (i.e., therapy) and with human subjects which introduces variables that cannot be controlled or measured. However, research such as the current study that examine processes and outcomes within naturalistic settings with 'real life' participants (i.e., patients in the NHS) have strong ecological validity and are arguably most useful for clinical practice. Using a repeated single-case design and data analysis such as SMA allowed the researcher to measure complex processes within therapy. A strength of the design is the multiple points and levels of measurement allowing rich data to be collected, enabling the researcher to apply an empirical and robust methodology to a clinical practice setting (Borckardt et al., 2008).

4.3.2 Problems with Measuring Working Alliance.

In this study, working alliance was measured using participant and therapist versions of the WAI-SF. As with many standardised self-report measures there are limitations that must be considered. One of the key theoretical critiques of the working alliance concept is the emphasis on collaboration and consensus (Doran, 2016). Bordin's (1979) definition highlights the degree of agreement between client and therapist on the goals and tasks during therapy. Theorists have raised concerns that not enough attention is given to potential conflict or negative feelings in the alliance (Brenner, 1979). Cushman and Gilford (2000) also argue that the working alliance construct has become conflated with the idea of agreement and does not give necessary consideration to the alliance developing through conflict and confrontation, consequently mistaking client compliance for an authentic working alliance. The WAI-SF measures the three components of Bordin's conceptualisation of working alliance (bond, task and goal) and therefore does not give consideration to some of the factors discussed here. This may result in measurement error and researchers have noted that the way clients perceive the therapy relationship is not accurately captured by existing measures, such as the WAI-SF (Owen, Reese, Quirk, & Rodolfa, 2013). Doran, Safran, Waizmann and Muran (2012) highlight that whilst the WAI-SF has some negatively worded items, there are a lack of items that focus on the degree of tension or conflict in the therapy relationship. Some of the limitations of the WAI-SF must be considered when drawing conclusions from the results of this study. Also, as presented in the working alliance data in the current study, there is a lack of variability in the reporting of working alliance. Furthermore, ratings are often high from the first therapy session (prior to formulations being introduced) and are generally maintained at similar levels throughout the intervention. Consequently, this creates difficulties when trying to detect any changes in the alliance when formulations are delivered (i.e., working alliance is reported high during early assessment sessions when the formulation frequency is low or even absent).

4.4 Strengths and Implications for Clinical Practice

Reviews of existing literature surrounding formulation (Aston, 2009; Bieling & Kuyken, 2003), would suggest that the current study is the first to measure the impact of CBT formulation on working alliance and secondary outcomes using a single-case design and analyses such as SMA. Consequently, this study offers a valuable contribution to the dearth of published research and can offer several implications for clinical practice.

As previously discussed, formulation is a competency central to clinical psychology training and practice (DCP, 2010). The findings of this study are complex and in summary there was no conclusive evidence to suggest that the utility of formulation in CBT impacts on or correlates with outcomes. There are limitations to the generalisability of findings (i.e., small sample size, difficulty controlling confounding variables), however the results may encourage Clinical Psychologists to reflect on why we deliver psychological formulation when there is such a limited evidence-base and whether the benefits of formulation lie with the client, the therapist or both. The findings of this study supports existing research that shows clients have mixed emotional responses to the formulation process. This offers an important clinical implication and suggests that clinicians should be attuned to the potentially distressing experience of receiving a formulation. Additionally, the findings suggest that the distress associated with receiving a formulation is not permanent and can be worked through using the containment of an effective working alliance. This further emphasises the importance of establishing a positive alliance within therapy and clinicians should possibly measure the working alliance to ensure that one is established prior to delivering a formulation.

Despite the complexity of findings in this study, it encourages a critical discussion and reflections surrounding the utility of psychological formulation in practice. It also highlights the complexity of psychotherapy research and the challenge of separating out processes which potentially overlap with each other. Clinical psychologists may want to consider whether it is possible to deliver CBT without sharing a formulation (process or product) or whether when delivering a

formulation is this also contributing to the working alliance. A significant strength of this study is that it opens up new ideas and opportunities for future research which will hopefully continue to develop our understanding of the mechanisms and impact of psychological formulation in practice.

4.5 Future Research

The current study contributes to a paucity in the literature surrounding the impact of psychological formulation on working alliance and psychosocial outcomes. The findings discussed here provide a strong platform for future research into formulation.

An area of interest that the current study did not investigate was measuring the accuracy of psychological formulations delivered and whether this had any impact on outcomes measured. Future studies should consider how accuracy is defined and whether a top down or bottom up approach is taken to examine this. For example, accuracy could be defined as the coherence to the theoretical model or it may also be defined as the perceived level of accuracy of the formulation from the participant's perspective (i.e., does it accurately reflect their experiences). Future research may wish to consider participant's behavioural responses following a process or product formulation, for example, verbal indicators which may suggest that the participant agrees or disagrees with the formulation shared. Measuring the accuracy of formulations delivered alongside outcome measures, such as, working alliance, measure of distress may provide the opportunity to investigate whether accuracy co-varies with these variables (i.e., formulation and outcomes such as, working alliance, low mood, wellbeing). As discussed previously, there are limitations to measuring the working alliance using alliance measures, such as the WAI-SF. Future researchers may wish to consider additional methods of measurement, for example, an observational schedule.

5. Critical Reflections

This section offers my clinical reflections on the research process, focussing on the development and refinement of the study, how the scientist practitioner model shaped my decisions on the study design and a reflection on some of the challenges I faced. Also, I will present my reflections on the theoretical and clinical contributions I believe this study offers, providing a platform for future research into psychological formulation.

5.1 Development of Study Ideas and Motivation for Area of Research

I initially felt overwhelmed with the vast choice of research topics and it took me some time to narrow down my interests. Something that was particularly important to me was to ensure that I picked a research area that was clinically relevant and also something that I felt passionate about, that I would be able to take forward after clinical training. In my clinical experience prior to training and during the teaching on the course, I noticed that psychological formulation was a core area of my practice and also central to the teaching we received. As a clinician, personally I thought that the process of formulation was helpful for me to organise my theoretical and clinical understanding of the clients I worked with but also (possibly naively) I assumed that formulation was also beneficial for my clients. After reading more around the literature and guidelines, I was astounded by the lack of evidence to support the utility of formulation, particularly as we align ourselves with the scientist-practitioner model. There is a clear need for further research into formulation in order to ensure that we are delivering evidence-based practice.

The complexity of researching psychological formulation was something I underestimated and a great deal of time and thought was given to design a study that considered some of the challenges faced in previous studies. I initially intended to undertake a qualitative study exploring the value of psychological formulation for clients and therapists, however after considering some of the methodological and conceptual challenges of researching formulation, I decided that the study would benefit from being more specific and a qualitative study would have possibly been too open and broad. I went

through a long process of refining and narrowing my research question/s to ensure it was clear what I was measuring and how I would measure it. For example, initial questions I considered were; 'is sharing a formulation helpful?', 'does formulation work?' and 'how and why is formulation helpful?'. I decided that assuming that formulation is helpful without the literature to support this would result in a researcher bias and I needed to be clear on how I would measure a formulation if it 'worked'. Moving forward with these initial ideas, I spent a long time considering how I would define formulation, how does formulation occur in clinical practice and how would I know when a formulation is being delivered, what dependant variables I would measure and how I could ensure reliability and ecological validity in the study. I gave a lot of thought to how formulation is truly delivered in clinical practice, in busy services where clinical psychologists have less time to develop formulations in accordance with good practice guidelines (BPS, 2011). During my first year placement, in an adult psychology service, I spoke to clinical psychologists about how they deliver psychological formulations in practice. Most said that they often did not deliver formulation in a 'formal way' (unless delivering Cognitive Analytic Therapy) but they weaved the formulation throughout their psychotherapeutic intervention. Some of these preliminary discussions encouraged me to think about how I could design a study that could measure formulation within therapy and further highlighted the importance of clearly defining how formulation will be delivered (e.g., as a process and/or product).

Researching psychological formulation within therapy is very interesting and complex, although at times I felt perplexed. A challenge I faced was ensuring that I did not design a study that was beyond a realistic timeframe of the clinical doctorate. I found that remaining focused on the research aims and questions of this study was occasionally very difficult, as further questions occurred throughout. For example, does the accuracy of process formulations impact on outcome? Supervision meetings had a tendency to go off on tangents, often due to the excitement and enthusiasm about the study and the opportunity for future research.

5.2 Reflection on the Study Design

The more literature I read on formulation, I became increasingly aware of the conceptual and methodological challenges of measuring formulation within psychotherapy. I found that using a SCD was ideal to measure such complex processes in a scientific and systematic way. I enjoy undertaking the role of a scientist-practitioner and I feel that my experience of using a SCD in this study allowed me to bridge the gap between research and clinical practice. Choosing a study design that enabled me to translate research into something that is clinically relevant was very important to me and I feel that this was one factor that maintained my interest throughout the research process.

However, this was my first experience of conducting a SCD and prior to clinical training, the majority of my research experience was using qualitative methodologies and I initially felt overwhelmed by all the different components of the design. Using a SCD fitted well with my epistemological position (critical realism) and also with the area of research, particularly as it encourages the researcher to remain critical of the variables being tested.

5.3 Reflection on the Process of Data Collection and Therapy

When designing the study, I spent some time thinking about whether I should deliver the therapy myself (giving myself a dual role of researcher and therapist) or whether I should attempt to recruit clinical psychologists who would be willing to follow my study procedure. Due to concerns that recruiting psychologists who have the time and capacity to do this might be very difficult, I agreed with my supervisors that I would take on the role as therapist.

On reflection, I think I underestimated the demand of delivering the therapy myself, alongside other commitments, such as placement and academic deadlines. This was compounded by recruitment difficulties and I was significantly behind schedule, only finishing data collection in December 2017. Juggling these demands along with delivering therapy for the research and receiving 90 minutes of additional CBT supervision was extremely stressful and resulted in periods where I felt burnt out. However, after having some time to

reflect, I don't think that I would have changed my decision. I feel that being the therapist provided me with a unique insight and understanding of my participants and I was able to discuss and reflect on some of the idiosyncrasies in the data. Also, I think being the sole therapist meant that factors such as therapist effects, were able to be controlled for.

5.4 Reflection on Data Analysis and Interpretation

As previously commented on, I initially felt overwhelmed with the sheer amount of data collected. An arduous task was coding the frequency of process formulations throughout sessions. This involved me listening back to audio recordings of every session, with each participant and coding the time and number of process formulations. Similarly to delivering the therapy, on reflection I think I underestimated how tiring and lengthy this process would be (i.e., 41 hours of data coding). Although criteria of how process formulations would be coded was clearly defined from the outset, at times it was difficult to ascertain whether I had included the three components and therefore required me to playback sections multiple times.

In addition to coding the frequency of process formulations, I completed the CTRS for every session with each participant. I found the CTRS difficult to use as items on the rating scale were not clearly defined and at times, some items were not relevant for that particular session and therefore a score of zero would be given for the item, pulling down the total rating for the session. For example, during initial sessions, items such as 'application of cognitive behavioural techniques' were not relevant but the CTRS does not exclude them from the administration.

I found the interpretation of results an interesting but very challenging process. The results of the study showed very little consistency across participants and I found it very difficult to understand and synthesise my results in relation to the research questions. In the midst of data analysis and interpretation I found that I was so immersed in the data that I struggled to see beyond the subtle nuances of the data. I noticed that I was trying to search for findings or the meaning behind findings, when potentially there was none, which

resulted in lengthy discussions in supervision meetings. Disentangling formulation from specific and non-specific processes at times felt an impossible task. Not having concrete or conclusive results felt anxiety provoking and I was overwhelmed with the possible explanations as to why variables may have or may not have correlated.

5.5 Reflection on CBT Supervision and Delivering CBT

I received 90 minutes of weekly CBT focussed supervision, which was a really valuable learning process. Initially supervision sessions felt quite intense as listening back to audio recordings (using a stop/start method) felt exposing. I reflected feeling anxious that my supervisor would think that I was incompetent and at times I felt compelled to avoid listening to audio recordings with him. I applied the CBT model to formulate my response and identified that early supervision meetings seemed to trigger my core belief that “I am not good enough”, which resulted in feeling anxious. However, as time passed, my anxiety reduced and my learning experiences excelled. In my reflective logs, I commented on feeling more confident in my ability to apply cognitive behavioural theory and I think this translated into my clinical practice; not just with research participants but also with clients on placement. As my confidence progressed, I recall delivering more process formulations during sessions and listening back to the audio recordings, the formulations seemed to flow more naturally. Although this study has not measured the confidence of the therapist, I wondered whether an improvement in confidence correlated with an increased frequency of process formulations. Also, I would be interested to investigate whether the accuracy of process formulations correlated with an increase or decrease in engagement with the client or correlated with outcomes.

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Appendix A: Working Alliance Inventory – Short Form

Working Alliance Inventory

Short Form (Participant Version)

Instructions

On the following pages there are sentences that describe some of the different ways a person might think or feel about his or her therapist (counsellor). As you read the sentences mentally insert the name of your therapist (counsellor) in place of _____ in the text.

Below each statement inside there is a seven point scale:

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

If the statement describes the way you always feel (or think) circle the number 7; if it never applies to you circle the number 1. Use the numbers in between to describe the variations between these extremes.

1. _____ and I agree about the things I will need to do in therapy to help improve my situation.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

2. What I am doing in therapy gives me new ways of looking at my problem.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

3. I believe _____ likes me.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

4. _____ does not understand what I am trying to accomplish in therapy.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

5. I am confident in _____ 's ability to help me.

1	2	3	4	5	6	7
---	---	---	---	---	---	---

Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always
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6. _____ and I are working towards mutually agreed upon goals.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

7. I feel that _____ appreciates me.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

8. We agree on what is important for me to work on.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

9. _____ and I trust one another.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

10. _____ and I have different ideas on what my problems are.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

11. We have established a good understanding of the kind of changes that would be good for me.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

12. I believe the way we are working with my problem is correct.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

Working Alliance Inventory

Short Form (Therapist Version)

Instructions

On the following pages there are sentences that describe some of the different ways a person might think or feel about his or her client. As you read the sentences mentally insert the name of your client in place of _____ in the text.

Below each statement inside there is a seven point scale:

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

If the statement describes the way you ***always*** feel (or think) circle the number 7; if it ***never*** applies to you circle the number 1. Use the numbers in between to describe the variations between these extremes.

1. _____ and I agree about the steps to be taken to improve his/her situation.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

2. My client and I both feel confident about the usefulness of our current activity in therapy.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

3. I believe _____ likes me.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

4. I have doubts about what we are trying to accomplish in therapy.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

5. I am confident in my ability to help _____.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

6. We are working towards mutually agreed upon goals.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

7. I appreciate _____ as a person.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

8. We agree on what is important for _____ to work on.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

9. _____ and I have built a mutual trust.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

10. _____ and I have different ideas on what his/her real problems are.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

11. We have established a good understanding between us of the kind of changes that would be good for _____.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

12. _____ believes the way we are working with her/his problem is correct.

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

Appendix B: PROMIS Depression Measure

In the past 7 days....		Never	Rarely	Sometimes	Often	Always
EDDEP04	I felt worthless.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP05	I felt that I had nothing to look forward to.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP06	I felt helpless.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP17	I felt sad.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP22	I felt like a failure.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP29	I felt depressed.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP36	I felt unhappy.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP41	I felt hopeless	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Appendix C: Mental Health Continuum – Short Form

Please answer the following questions are about how you have been feeling during the past week and check mark in the box that best represents how often you have experienced or felt the following:

	Never	Once or Twice	About Once a Week	About 2 or 3 Times a Week	Almost Every Day	Every Day
During the past week, how often did you feel						
<hr/>						
1. happy						
2. interested in life						
3. satisfied						
4. that you had something important to contribute to society						
5. that you belonged to a community (like a social group, or your neighborhood).						

**6. that our society is
becoming a better place
for people like you.**

**7. that people are
basically good.**

**8. that the way our society
works makes sense to
you**

**9. that you liked most
parts of your personality.**

**10. good at managing the
responsibilities of your
daily life**

**11. that you had warm
and trusting relationships
with others.**

**12. that you had
experiences that
challenged you to grow
and become a better
person.**

**13. confident to think or
express your own ideas
and opinions.**

**14. that your life has a
sense of direction or
meaning to it**

Appendix D: CORE-OM

Over the last week		Not at all	Only Occasionally	Sometimes	Often	Most or all the time	ORCID use only
1	I have felt terribly alone and isolated	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> F
2	I have felt tense, anxious or nervous	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> P
3	I have felt I have someone to turn to for support when needed	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> F
4	I have felt OK about myself	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> W
5	I have felt totally lacking in energy and enthusiasm	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> P
6	I have been physically violent to others	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> R
7	I have felt able to cope when things go wrong	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> F
8	I have been troubled by aches, pains or other physical problems	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> P
9	I have thought of hurting myself	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> R
10	Talking to people has felt too much for me	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> F
11	Tension and anxiety have prevented me doing important things	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> P
12	I have been happy with the things I have done	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> F
13	I have been disturbed by unwanted thoughts and feelings	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> P
14	I have felt like crying	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> W

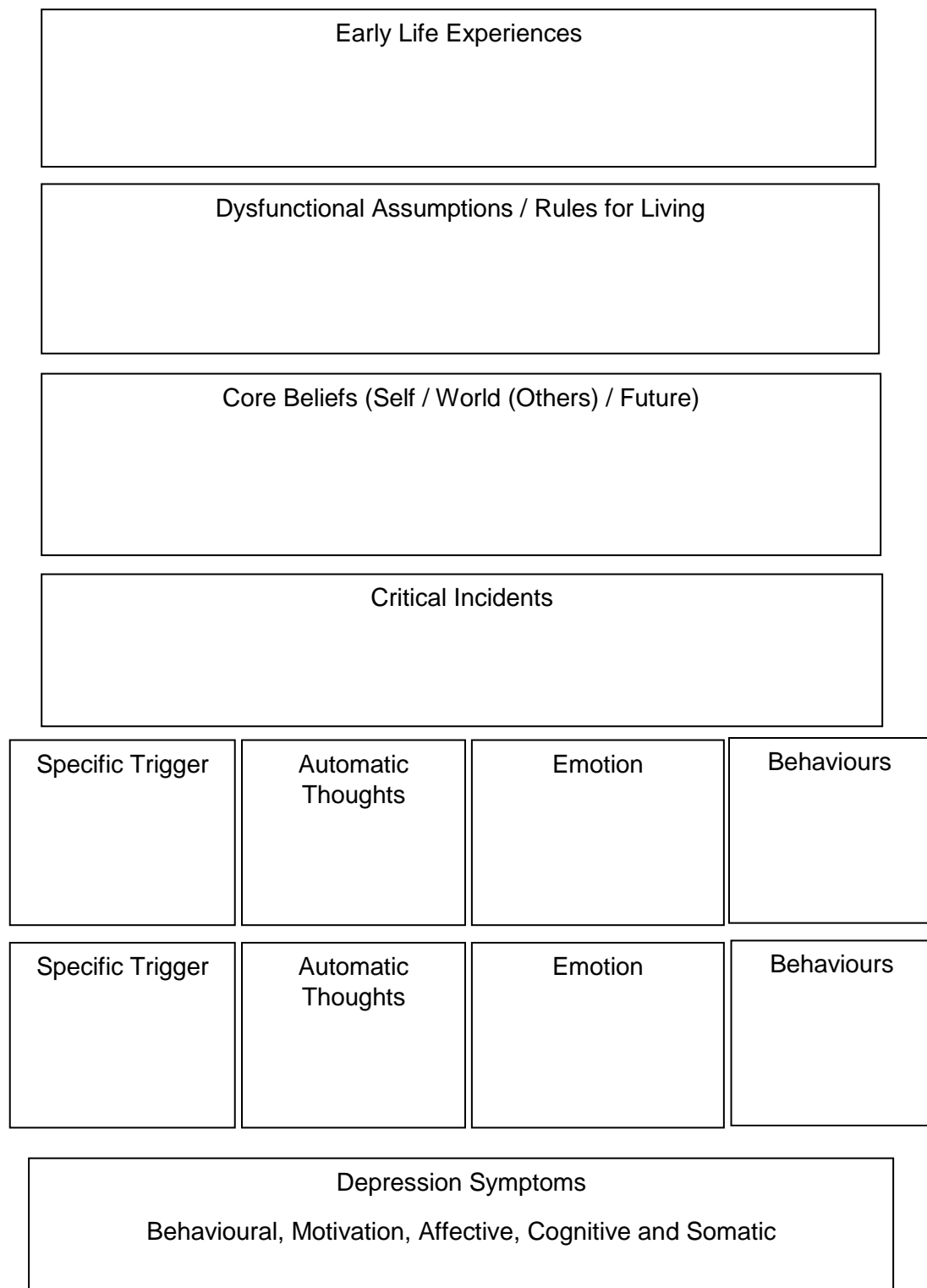
15 I have felt panic or terror	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	P
16 I made plans to end my life	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	R
17 I have felt overwhelmed by my problems	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	W
18 I have had difficulty getting to sleep or staying asleep	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	P
19 I have felt warmth or affection for someone	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/>	F
20 My problems have been impossible to put to one side	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	P
21 I have been able to do most things I needed to	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/>	F
22 I have threatened or intimidated another person	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	R
23 I have felt despairing or hopeless	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	P
24 I have thought it would be better if I were dead	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	R
25 I have felt criticised by other people	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	F
26 I have thought I have no friends	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	F
27 I have felt unhappy	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	P
28 Unwanted images or memories have been distressing me	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	P
29 I have been irritable when with other people	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	F
30 I have thought I am to blame for my problems and difficulties	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	P
31 I have felt optimistic about my future	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/>	W
32 I have achieved the things I wanted to	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/>	F
33 I have felt humiliated or shamed by other people	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	F
34 I have hurt myself physically or taken dangerous risks with my health	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>	R

Appendix E: Process Formulation Record Sheet

A process formulation will be coded if: All three components Antecedent (A), Belief (B) and Consequence (C) are present, occurring in any order.

Participant Number	Session Number & Date	Frequency and timing of Process Formulations	Cognitive Therapy Rating Scale Items 1-9	Rating (0-6)
		<input type="checkbox"/> Time:	1. Agenda	
		<input type="checkbox"/> Time:	2. Feedback	
		<input type="checkbox"/> Time:	3. Understanding	
		<input type="checkbox"/> Time:	4. Interpersonal Effectiveness	
		<input type="checkbox"/> Time:	5. Collaboration	
		<input type="checkbox"/> Time:	6. Pacing and Efficient Use of Time	
		<input type="checkbox"/> Time:	7. Guided Discovery	
		<input type="checkbox"/> Time:	8. Focusing on Key Cognitions or Behaviours	
		<input type="checkbox"/> Time:	9. Strategy for Change	
		<input type="checkbox"/> Time:	10. Application of Cognitive-Behavioral Techniques	
		<input type="checkbox"/> Time:	11. Homework	
		Total Count:		

Appendix F: Product Formulation – Longitudinal CBT Model (Beck, 1979)



Appendix G: Change Interview Schedule

Introduction

The interviewer will thank the participant for their time and taking part in the study. The interviewer will explain the aims of this interview, which are to gain an understanding of the participant's experience of therapy and the process of formulation, considering helpful and unhelpful aspects.

Part One: Experiences of Therapy

1. Have you had therapy previously to seeing Hannah?

Prompts: If so, what type of therapy?

Do you think the therapy influenced your expectations of therapy?

2. Tell me about your experiences of the therapy you have received from Hannah.

Prompts: Were there any aspects that you found helpful/positive or unhelpful/negative? Why did you find these helpful/positive or unhelpful/negative?

3. Have you noticed any changes (better or worse) in yourself since you started and ended therapy?

Prompts: Any changes in thoughts, feelings, behaviours and circumstances? What do you think has contributed to your changes (inside and outside of therapy)?

Part Two: Experiences of Formulation

4. Tell me about your understanding/experiences of formulation

Prompts:

Have you had a formulation? If they say no, say: Psychologists often make links between past experiences and how these have shaped thoughts/beliefs, feelings and behaviours. This aims to explain how your main problems have developed and how they are being maintained.

Tell me about your experiences of the formulation that Hannah drew out with you. (Product Formulation)

Tell me about your experiences of aspects of your formulation that Hannah has discussed verbally with you. (Process ABCs)

5. Were there any aspects of your formulation that you found helpful or unhelpful? If so, what were they?

Prompts: Was it helpful/unhelpful with your difficulties? Why were they helpful/unhelpful?

Ending

Thank the participant for their time and ask whether there is anything they would like to ask.

Appendix H: REC Approval Letter, 7th March 2017



Health Research Authority

East Midlands - Nottingham 1 Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

07 March 2017

Miss Hannah Daniels
Lincolnshire Partnership Foundation Trust
Bridge House, Doctorate in Clinical Psychology
Brayford Pool,
Lincoln
LN6 7TS

Dear Miss Daniels.

Study title:	Exploring the impact of psychological formulation on working alliance: a mixed methods, repeated single case investigation
REC reference:	17/EM/0070
IRAS project ID:	221260

Thank you for your letter of 03 March 2017, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ('participant identification centre'), guidance should be sought from the R&D office on the information it requires to give permission for this activity

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering letter on headed paper [Cover Letter]	1	16 January 2017
Covering letter on headed paper [Cover Letter - REC Response]	2	01 March 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance/Indemnity Certificate]	1	23 January 2017
Interview schedules or topic guides for participants [Interview Schedule]	1	27 January 2017
IRAS Application Form [IRAS_Form_30012017]		30 January 2017
IRAS Checklist XML [Checklist_03032017]		03 March 2017
Other [Participant Debrief Sheet]	1	16 January 2017
Other [Product Formulation Model]	1	16 January 2017
Other [Intervention/Therapy plan]	1	03 January 2017
Other [Transcriber Confidentiality Agreement Form]	1	26 January 2017
Other [Service Inclusion/Exclusion Criteria]	1	03 January 2017
Other [Overview of Study for Participants]	1	02 March 2017
Participant consent form [Consent Form]	2	01 March 2017
Participant information sheet (PIS) [Participant Information Sheet 28.02.2017]	2	28 February 2017
Research protocol or project proposal [Research Protocol]	1	27 January 2017
Summary CV for Chief Investigator (CI) [Chief Investigator CV]	1	23 January 2017
Summary CV for supervisor (student research) [DDawson CV]	1	15 January 2017
Summary CV for supervisor (student research) [MGresswell CV]	1	03 January 2017
Summary CV for supervisor (student research) [LBraham CV]	1	16 January 2017
Validated questionnaire [Beck Depression Inventory]	1	
Validated questionnaire [CORE]	1	16 January 2017
Validated questionnaire [Mental Health Continuum]	1	16 January 2017
Validated questionnaire [Working Alliance Inventory - Client Version]	1	15 January 2017
Validated questionnaire [Working Alliance Inventory - Therapist Version]	1	15 January 2017

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

17/EM/0070

Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project.

Yours sincerely,



Mr John Aldridge
Chair

Appendix I: REC Substantial Approval Letter, 14th July 2017



Health Research Authority

East Midlands - Nottingham 1 Research Ethics Committee

The Old Grace
Roya Standard Place
Nottingham
NG1 6FE

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

14 July 2017

Miss Hannah Daniels
Trainee Clinical Psychologist
Lincolnshire Partnership Foundation Trust
Bridge House, Doctorate in Clinical Psychology
Brayford Pool
Lincoln
LN6 7TS

Dear Miss Daniels

Study title:	Exploring the impact of psychological formulation on working alliance: a mixed methods, repeated single case investigation
REC reference:	17/EM/0070
Amendment number:	1
Amendment date:	03 July 2017
IRAS project ID:	221260

The above amendment was reviewed at the meeting of the Sub-Committee held in correspondence on 11 July 2017

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation

The documents reviewed and approved at the meeting were

Document	Version	Date
Notice of Substantial Amendment (non-CT MP)	*	03 July 2017
Other (Overview of Study for Participants)	2	03 July 2017
Participant information sheet (PIS)	2	03 July 2017
Research protocol or project proposal	2	03 July 2017
Validated questionnaire (PROMS short Form Depression Measure)	*	03 July 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study

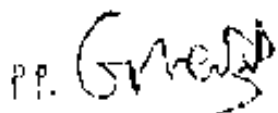
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/ria-training/>

17/EM/0070: Please quote this number on all correspondence
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Yours sincerely



Chair

E-mail: NRESCCommittee.EastMidlands-Nottingham1@nhs.net

Enclosures List of names and professions of members who took part in the review

Copy to R&D - Mrs Tracy McCranor, Lincolnshire Partnership NHS Foundation Trust
Dr Sara Owen

Appendix J: REC Substantial Approval Letter, 12th September 2017

East Midlands - Nottingham 1 Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

12 September 2017

Hannah Daniels

Dear Hannah

Study title:	Exploring the impact of psychological formulation on working alliance: a mixed methods, repeated single case investigation
REC reference:	17/EM/0070
Amendment number:	2
Amendment date:	11 September 2017
IRAS project ID:	221260

The above amendment was reviewed at the meeting of the Sub-Committee held in correspondence on 12 September 2017

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Committee agreed to approve the concept of home visits in general and not just for the specific patient referenced in the amendment.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMP) [REC Amendment	2	11 September 2017

Form: pdf]		
Participant information sheet (PIS; [Participant Information Sheet: 11.08.2017.docx])	4	1 st September 2017
Research protocol or project proposal [Research Protocol: 11.08.2017.docx]	3	1 st September 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra/training/>

17/EM/0070:	Please quote this number on all correspondence
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Yours sincerely



Mr Murthy Nyasavajjala
Chair

E-mail: NRESCommittee.EastMidlands-Nottingham1@nhs.net

Enclosures *List of names and professions of members who took part in the review*

Copy to *Mrs Tracy McCranor, Lincolnshire Partnership NHS Foundation Trust*
Miss Hannah Daniels, Lincolnshire Partnership Foundation Trust
Dr Sara Owen

Appendix K: REC Substantial Approval Letter, 26th February 2018

East Midlands - Nottingham 1 Research Ethics Committee

The Old Chase
Royal Standard Place
Nottingham
NG1 6FE

26 February 2018

Miss Hannah Daniels
College of Social Science
Ground Floor, Bridge House
University of Lincoln
Brayford Pool
Lincoln
LN6 7TS

Dear Miss Daniels,

Study title:	Exploring the impact of psychological formulation on working alliance: a mixed methods, repeated single case investigation
REC reference:	17/EM/0070
Amendment number:	3
Amendment date:	17 February 2018
IRAS project ID:	221260

Thank you for submitting the above amendment which was received on 22 February 2018. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMP)	3	17 February 2018
Participant consent form	-	17 February 2018
Research protocol or project proposal	4	17 February 2018

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

We are pleased to welcome researchers and R & D staff at our Research Ethics Service Committee members training days – see details at <http://www.hra.nhs.uk/hra-training/>

17/EM/0070:

Please quote this number on all correspondence

Yours sincerely



Daniella Sarno
REC Assistant

Email: NRESCommittee.EastMidlands-Nottingham1@nhs.net

Copy to: *Mrs Tracy McCranor*

Appendix L: Health Research Authority Approval

Health Research Authority

Miss Hannah Daniels
Trainee Clinical Psychologist
Lincolnshire Partnership Foundation Trust
Bridge House, Doctorate in Clinical Psychology
Brayford Pool,
Lincoln LN6 7TS

Email: hra.approval@nhs.net

07 March 2017

Dear Miss Daniels

Letter of HRA Approval

Study title: Exploring the impact of psychological formulation on working alliance: a mixed methods, repeated single case investigation
IRAS project ID: 221260
REC reference: 17/EM/0070
Sponsor: University of Lincoln

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
 - *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
 - *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.
-

Appendix M: School of Psychology Ethics Committee, University of Lincoln Approval

Hi,

This is to confirm that your application titled *Exploring the impact of psychological formulation on working alliance: a mixed methods, repeated single case investigation* which was submitted for ethical approval, has been Conditionally approved by the School of Psychology Research Ethics Committee.

The following conditions must be met before approval can be granted:

- In debrief please add soprec@lincoln.ac.uk email to withdraw data and to contact if any ethical issues.

This does not need to be seen by the committee. Once your supervisor has seen it you can commence data collection.

Kind regards,
Matt

Soprec

1 of 2 ▲ ▼

Appendix N: Participant Consent Form

Title of Study: Exploring the impact of psychological formulation on working alliance: a mixed methods, repeated single case investigation

REC Ref: 221260

Name of Researcher: Hannah Daniels

Name of Participant:

I confirm that I have read and understand the information sheet version number 2 dated 01.03.2017 for the above study and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far can be erased if I request this within two weeks after I withdraw from the study. I also understand that if I wish to withdraw after I have completed the study, I have two weeks from completion to request this

I understand that data collected in the study may be looked at by authorised individuals from the University of Lincoln, the research team and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential.

I understand that if I lose the capacity to consent at any point, I will be withdrawn from the study. Data that has already been collected will be retained and no further data will be collected.

I understand that my therapist will discuss the content of therapy sessions, during supervision, with her supervisor, who is a member of the direct care team.

I understand that if I disclose information that raises concern that I am a risk of harm to myself, to others or from other, my therapist may need to discuss this with third parties, such as, her supervisor, safeguarding team, police.

As part of the study, I agree to have my therapy sessions audio recorded for the purpose of data analysis.

I understand that a professional transcriber will listen to and transcribe the end of therapy interviews. The transcriber will sign a confidentiality agreement.

I agree to take part in the above study.

.....
Name of Participant	Date	Signature

.....
Name of Person Taking Consent	Date	Signature

When completed, copies for: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes

Appendix O: Participant Information Sheet

IRAS ID Number: 221260

Title of Study:

Exploring the impact of psychological formulation on working alliance: a mixed methods, repeated single case investigation.

Name of Researcher: Hannah Daniels

Name of Research Supervisors:

Dr Mark Gresswell, Dr Dave Dawson and Dr Louise Braham

I would like to invite you to take part in my research study. Before you decide I would like you to understand why the research is being done and what it would involve for you. I will go through the information sheet with you and answer any questions you have. Feel free to talk to others about the study if you wish and ask me if there is anything that is not clear.

What is the purpose of the study?

The main purpose of this study is to investigate whether formulation impacts on the working alliance between the therapist and client. The study will also investigate whether formulation impacts other outcomes, such as the intensity of depression experienced by the client and overall general well-being.

Formulation is a skill used by Clinical Psychologists and it aims to provide an explanation or ideas about how an individual's difficulties have developed and how they are being maintained. The formulation is developed together with your therapist and it might change over the course of therapy, if it is updated with new information. The psychologist will also use their skills to draw on psychological theory to help develop the formulation and will also use it to guide treatment.

Working alliance refers to the relationship between the therapist and the client. This is a two way process and is made up of several components, 1) the agreement on therapy goals, 2) the agreement on the target of the treatment and 3) the quality of the bond between the client and the therapist.

Why have I been invited?

You are being invited to take part because you are currently accessing the Community Mental Health Team (CMHT) and your care team have identified that psychological therapy might be beneficial for your treatment. You will be offered a well-known and evidence-based treatment called Cognitive Behaviour Therapy (CBT), which is commonly used for treating a range of mental health problems, including low mood and depression. CBT consists of psychological assessment, formulation and intervention and this study is particularly interested in how formulation impacts on outcomes, such as working alliance and symptoms of low mood.

This means that if you take part in the study, you will not be receiving a treatment that is different or new but the study will be measuring what processes are helpful in the treatment that you receive. We are inviting six participants who are receiving treatment in the CMHT.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

This study will be investigating the impact formulation has during your therapy that you will be receiving in the Community Mental Health Team. Your sessions will be delivered by the researcher, who is a Trainee Clinical Psychologist at the University of Lincoln. Your sessions will take place on a weekly basis, lasting for one hour and will be held at the (enter clinic base name – dependant on which CMHT the participant is recruited from) or the researcher can facilitate a home visit, if you are unable to travel to the clinic base. As mentioned previously, the treatment you receive will be orientated around CBT, which has a strong evidence base and is recommended in published guidelines. This study will be investigating the processes that occur during CBT, one of these is formulation. To investigate this, we will be offering eight sessions of assessment, formulation and CBT. Your sessions will be audio-recorded so that the researchers can listen back to them and count the number of times a formulation is delivered.

We are asking for your consent for the following:

- To audio-record your psychology sessions
- To complete one questionnaire, three times, prior to beginning therapy.
- To complete three questionnaires at the end of each session

- To take part in an interview after your therapy.

Audio-recording sessions will allow the researcher to measure how often formulations are delivered during therapy and how it effects the outcomes of your therapy. The audio-recordings will be listened to by your therapist and her supervisor who works in the NHS.

After each session, you will be asked to complete three questionnaires, which should take you between five and ten minutes to complete. You will also be asked to complete 1 questionnaire at your first and last session, this is a service-standard measure.

Once you have completed your eight sessions of therapy, the researcher will ask you to take part in an end of therapy interview. This will take between 40 - 60 minutes and you will be given the opportunity to share your experiences of receiving a formulation. This will be with someone external to the research team, such as another Trainee Clinical Psychologist.

Expenses and payments

Participants will not be paid to participate in the study. Travel expenses will be offered for participants to attend the (enter clinic base name) for the end of therapy interview only because the therapy you receive is the treatment as usual offered to you in the psychology service.

What are the possible disadvantages and risks of taking part?

On occasions psychological therapy may require you to talk about some of your difficulties and topics that may be sensitive and personal. Your therapist is trained to support you and guide you through therapy and also receives weekly supervision to discuss any difficulties if they arise.

What are the possible benefits of taking part?

We cannot promise the study itself will help you but the information we get from this study may help contribute to the evidence on whether formulation has any benefits for clients. It may also contribute to the training that Clinical Psychologists receive, which

is particularly important to ensure that psychologists are developing skills that are helpful for clients that they work with.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting:

School of Psychology Research Ethics Committee (SOPREC)

College of Social Science

University of Lincoln

Brayford Pool

Lincoln

Lincolnshire

LN6 7TS

Email: soprec@lincoln.ac.uk

Patient Advice and Liaison Service (PALS)

Tel: 01529 222265

Email: PALS@lpft.nhs.uk

Will my taking part in the study be kept confidential?

All data that is collected during this study will be anonymised and kept confidential. Access to the data will be kept to a minimum and will be seen only by a small number of people, including the researcher, research supervisors and authorised individuals at the University of Lincoln.

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Lincoln who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty. A professional transcriber will be used to transcribe

the end of therapy interviews. They will also have a duty of confidentiality and will sign a confidentiality agreement with the lead researcher.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the clinic will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept on the secure patient administration system in Lincolnshire Partnership Foundation NHS Trust. At the end of the study, we will obtain these so that we are able to contact you about the findings of the study. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in your psychology sessions and in the end of therapy interview is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons. This will include the therapist discussing her concerns with their supervisor and may also be taken forward to third parties, such as the safeguarding team, crisis team or the police. The therapist will also discuss some of the content of your sessions during weekly supervision, with her supervisor, who is a member of the direct care team.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your care being affected. If you wish to withdraw after the study has finished, you can do this within two weeks of completing. If you withdraw during or after the study, you can request that information collected so far to be erased, if you request this within two weeks after withdrawing.

You can withdraw from the study in two ways; firstly by requesting this through the lead researcher (Hannah Daniels) or secondly through the School of Psychology Ethics Committee (SOPREC). You can contact SOPEC on soprec@lincoln.ac.uk and you must provide them with your participant ID code and the name of the study. SOPREC

will then arrange with the researcher that you wish to withdraw and data will be erased if this is requested within two weeks from withdrawal.

It is unlikely that you will lose capacity during the study, however if it is deemed that you lose capacity, at any point, you will be withdrawn from the study. Data that has already been collected will be retained, however no further data will be collected.

What will happen to the results of the research study?

A summary of the results of the study will be sent to you via the post if you wish to read them. The study will be written up as part of the researcher's Doctorate in Clinical Psychology qualification. It is also expected that the study will be published in an academic journal and may also be presented at conferences. All identifiable information will be removed in any reports, publications and presentations.

Who is organising and funding the research?

This research is being organised and funded by the University of Lincoln.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by [*please add name of committee submitting to*] Research Ethics Committee.

Further information and contact details

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Appendix P: Participant Debrief Sheet

Thank you for participating in this study which has investigated whether psychological formulation impacts on working alliance and other outcomes, e.g. severity of depression, general wellbeing. We appreciate your time and effort participating in the study and hope that the results will be useful for future clinical practice, treatment and training of Clinical Psychologists. Once the data has been analysed and interpreted, if you wish, we will send you the results of the study in the post.

Any personal information you have provided will remain confidential and all data analysed in the study will be anonymous, to ensure that you are unidentifiable. Following the end of the study, if you change your mind and wish to withdraw, please contact the lead researcher (details provided below). All data collected from you will be destroyed if you request this within two weeks of withdrawal.

If you have any further questions that you would wish to discuss, please feel free to contact the lead researcher or supervisors on the contact details provided. If you have experienced any distress during the study that you do not wish to discuss with us, please use the advice helplines outlined below.

Thank you once again for your time,

Hannah Daniels

Dr Mark Gresswell

Lead Researcher

Research Supervisor

Work Telephone: 07376 557784

Email: hannah.daniels@lpft.nhs.uk

Email: mark.gresswell@lpft.nhs.uk

Dr David Dawson

Research Supervisor

Email: ddawson@lincoln.ac.uk

Advice Helplines and Useful Links

Crisis Team: 0303 123 4000

Samaritans: 116123 or jo@samaritans.org or www.samaritans.org

Appendix Q: Cognitive Therapy Rating Scale

Cognitive Therapy Rating Scale (CTRS)

Directions: For each time, assess the therapist on a scale from 0 to 6, and record the rating on the line next to the item number. Descriptions are provided for even-numbered scale points. If you believe the therapist falls between two of the descriptors, select the intervening odd number (1, 3, 5). For example, if the therapist set a very good agenda but did not establish priorities, assign a rating of a 5 rather than a 4 or 6.

If the descriptions for a given item occasionally do not seem to apply to the session you are rating, feel free to disregard them and use the more general scale below:

- 0 – Poor
- 1 – Barely Adequate
- 2 – Mediocre
- 3 – Satisfactory
- 4 – Good
- 5 – Very Good
- 6 – Excellent

Please do not leave any item blank. For all items, focus on the skill of the therapist, taking into account how difficult the patient seems to be.

Part I. GENERAL THERAPEUTIC SKILLS

1 AGENDA

- 0 Therapist did not set agenda.
- 2 Therapist set agenda that was vague or incomplete.
Therapist worked with patient to set a mutually satisfactory agenda that included specific target problems (e.g., anxiety at work, dissatisfaction with marriage.)
- 4
- 6 Therapist worked with patient to set an appropriate agenda with target problems, suitable for the available time. Established priorities and then followed agenda.

2. FEEDBACK

- 0 Therapist did not ask for feedback to determine patient's understanding of, or response to, the session.
- 2 Therapist elicited some feedback from the patient, but did not ask enough questions to be sure the patient understood the therapist's line of reasoning during the session or to ascertain whether the patient was satisfied with the session.
- 4 Therapist asked enough questions to be sure that the patient understood the therapist's line of reasoning throughout the session and to determine the patient's reactions to the session. The therapist adjusted his/her behavior in response to the feedback, when appropriate.
- 6 Therapist was especially adept at eliciting and responding to verbal and non-verbal feedback throughout the session (e.g., elicited reactions to session, regularly checked for understanding, helped summarize main points at end of session).

3. UNDERSTANDING

- 0 Therapist repeatedly failed to understand what the patient explicitly said and thus consistently missed the point. Poor empathic skills.
- 2 Therapist was usually able to reflect or rephrase what the patient explicitly said, but repeatedly failed to respond to more subtle communication. Limited ability to listen and empathize.

- 4 Therapist generally seemed to grasp the patient's "internal reality" as reflected by both what the patient explicitly said and what the patient communicated in more subtle ways. Good ability to listen and empathize.
- 6 Therapist seemed to understand the patient's "internal reality" thoroughly and was adept at communicating this understanding through appropriate verbal and non-verbal responses to the patient (e.g., the tone of the therapist's response conveyed a sympathetic understanding of the patient's "message"). Excellent listening and empathic skills.

4. INTERPERSONAL EFFECTIVENESS

- 0 Therapist had poor interpersonal skills. Seemed hostile, demeaning, or in some other way destructive to the patient.
- 2 Therapist did not seem destructive, but had significant interpersonal problems. At times, therapist appeared unnecessarily impatient, aloof, insincere or had difficulty conveying confidence and competence.
- 4 Therapist displayed a satisfactory degree of warmth, concern, confidence, genuineness, and professionalism. No significant interpersonal problems.
- 6 Therapist displayed optimal levels of warmth, concern, confidence, genuineness, and professionalism, appropriate for this particular patient in this session.

5. COLLABORATION

- 0 Therapist did not attempt to set up a collaboration with patient.
- 2 Therapist attempted to collaborate with patient, but had difficulty either defining a problem that the patient considered important or establishing rapport.
- 4 Therapist was able to collaborate with patient, focus on a problem that both patient and therapist considered important, and establish rapport.
- 6 Collaboration seemed excellent; therapist encouraged patient as much as possible to take an active role during the session (e.g., by offering choices) so they could function as a "team".

6. PACING AND EFFICIENT USE OF TIME

- 0 Therapist made no attempt to structure therapy time. Session seemed aimless.
- 2 Session had some direction, but the therapist had significant problems with structuring or pacing (e.g., too little structure, inflexible about structure, too slowly paced, too rapidly paced).
- 4 Therapist was reasonably successful at using time efficiently. Therapist maintained appropriate control over flow of discussion and pacing.
- 6 Therapist used time efficiently by tactfully limiting peripheral and unproductive discussion and by pacing the session as rapidly as was appropriate for the patient.

Part II. CONCEPTUALIZATION, STRATEGY, AND TECHNIQUE

7. GUIDED DISCOVERY

- 0 Therapist relied primarily on debate, persuasion, or “lecturing.” Therapist seemed to be “cross-examining” patient, putting the patient on the defensive, or forcing his/her point of view on the patient.
- 2 Therapist relied too heavily on persuasion and debate, rather than guided discovery.

However, therapist’s style was supportive enough that patient did not seem to feel attacked or defensive.
- 4 Therapist, for the most part, helped patient see new perspectives through guided discovery (e.g., examining evidence, considering alternatives, weighing advantages and disadvantages) rather than through debate. Used questioning appropriately.
- 6 Therapist was especially adept at using guided discovery during the session to explore problems and help patient draw his/her own conclusions. Achieved an excellent balance between skillful questioning and other modes of intervention.

8. FOCUSING ON KEY COGNITIONS OR BEHAVIORS

- 0 Therapist did not attempt to elicit specific thoughts, assumptions, images, meanings, or behaviors.

- 2 Therapist used appropriate techniques to elicit cognitions or behaviors; however, therapist had difficulty finding a focus or focused on cognitions/behaviors that were irrelevant to the patient's key problems.
- 4 Therapist focused on specific cognitions or behaviors relevant to the target problem. However, therapist could have focused on more central cognitions or behaviors that offered greater promise for progress.
- 6 Therapist very skillfully focused on key thoughts, assumptions, behaviors, etc. that were most relevant to the problem area and offered considerable promise for progress.

9. STRATEGY FOR CHANGE *(Note: For this item, focus on the quality of the therapist's strategy for change, not on how effectively the strategy was implemented or whether change actually occurred.)*

- 0 Therapist did not select cognitive-behavioral techniques.
- 2 Therapist selected cognitive-behavioral techniques; however, either the overall strategy for bringing about change seemed vague or did not seem promising in helping the patient
- 4 Therapist seemed to have a generally coherent strategy for change that showed reasonable promise and incorporated cognitive-behavioral techniques.
- 6 Therapist followed a consistent strategy for change that seemed very promising and incorporated the most appropriate cognitive-behavioral techniques.
- 7

10. APPLICATION OF COGNITIVE-BEHAVIORAL TECHNIQUES *(Note: For this item, focus on how skillfully the techniques were applied, not on how appropriate they were for the target problem or whether change actually occurred.)*

- 0 Therapist did not apply any cognitive-behavioral techniques.
- 2 Therapist used cognitive-behavioral techniques, but there were significant flaws in the way they were applied.
- 4 Therapist applied cognitive-behavioral techniques with moderate skill.
- 6 Therapist very skillfully and resourcefully employed cognitive-behavioral techniques.

11. HOMEWORK

- 0 Therapist did not attempt to incorporate homework relevant to cognitive therapy.
- 2 Therapist had significant difficulties incorporating homework (e.g., did not review previous homework, did not explain homework in sufficient detail, assigned inappropriate homework).
- 4 Therapist reviewed previous homework and assigned “standard” cognitive therapy homework generally relevant to issues dealt with in session. Homework was explained in sufficient detail.
- 6 Therapist reviewed previous homework and carefully assigned homework drawn from cognitive therapy for the coming week. Assignment seemed “custom tailored” to help patient incorporate new perspectives, test hypotheses, experiment with new behaviors discussed during session, etc.

Impact of Psychological Formulation on Working Alliance

A Mixed Method Repeated Single Case Design

Hannah Daniels, Mark Gresswell, David Dawson & Louise Braham

Trent Doctorate in Clinical Psychology

Introduction

Background

Psychological formulation can be defined as a number of hypotheses that offer an explanation of the development and maintenance of a client's difficulties.¹ Formulation is a key process in many evidence-based psychological therapies and is outlined as a core competency in clinical psychology training and practice and within wider mental health professions.²

Despite the emphasis on formulation in clinical psychology, there is limited and inconsistent evidence to show that formulation improves outcomes of distress and the working alliance.^{3,4}

Reasons for an absence of evidence include; formulation is difficult to operationalise, it may look different across therapies and there are issues of quality and reliability. Also, it is difficult to disentangle formulation from processes such as specific factors of the therapeutic model and non-specific factors such as the working alliance.

Common factors approach suggests that if all factors are present (e.g., strong bond, safe space), any therapy regardless of the model will be effective. Research has shown that working alliance correlates with improved outcomes.⁵

Present Study

Aimed to examine and disentangle whether formulation drives outcomes (depression and wellbeing) or other non-specific processes (working alliance) in 8 sessions of CBT, targeting low mood.

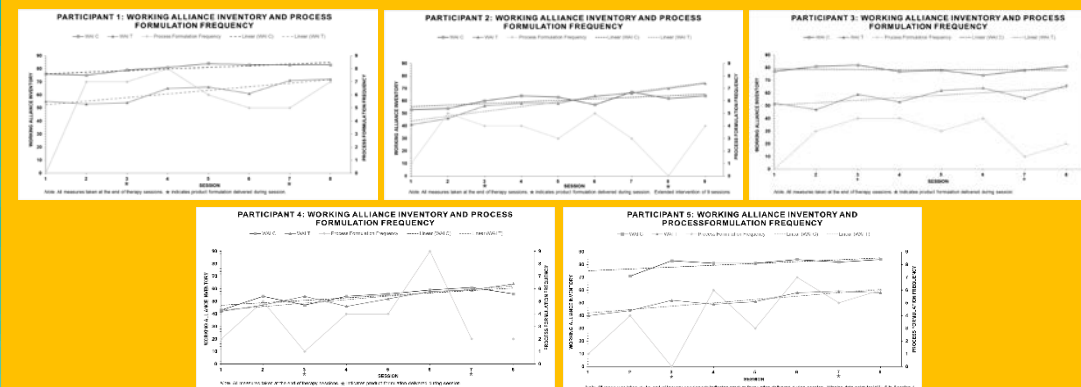
Results

Does Formulation Impact Working Alliance?

- Visual analysis showed slight peaks in participant working alliance (n=3) when product formulation was delivered but not consistent with therapist reports.
- SMA showed two significant correlations (at lag -1) between an improvement in working alliance and increased frequency of process formulations delivered in the next session.
- In change interviews, all participants talked about aspects of the alliance, but did not link this with formulation.

What is the relationship between Formulation, Working Alliance and Secondary Outcomes?

- Visual analysis and RC analyses showed some trend between formulation (process and product), depression and wellbeing but minimal replications across participants.
- SMA showed some correlations between variables but little repetition across participants.
- Participants reported mixed emotional reactions to the formulation.



Method

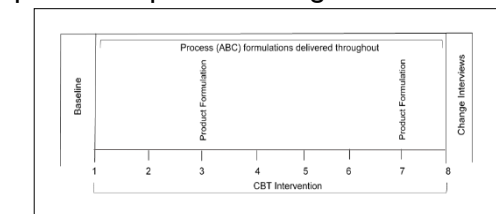
Study used a mixed method repeated single case design.

5 participants, recruited from community adult mental health team, all presenting with low mood.

Baseline phase (3 weeks) measuring low mood.

Received 8 weekly sessions of CBT focussing on low mood. Participants and therapist completed measures at end of each session.

Four participants took part in a change interview.



Formulation was delivered in two ways:

Process Formulation – Verbal summaries that aimed to assist understanding of difficulties, delivered at any point throughout CBT. Consisted of; antecedent (A), belief/cognition (B), consequence (C).

Product Formulation – Diagrammatic using Beck longitudinal model. Delivered twice (session 3 and 7).

Data Analysis

Process formulations were coded and frequency counted. Visual analysis and Simulation Modelling Analysis (SMA) undertaken. Reliable Change (RC) and Clinically Significant Change (CSC) calculated. Key themes identified in change interview data.

Aims

Study aimed to examine whether:

1. Formulation impacts on working alliance.
2. There is a relationship between formulation, working alliance and psychosocial outcomes.

Discussion

- Study showed a slight relationship between formulation and working alliance, but evidence not robust enough to confirm whether formulation directly impacts working alliance. Data shows mixed results in terms of the relationship between formulation, working alliance and psychosocial outcomes. Although some participants improved across measures at post-intervention, this could not be attributed to the formulation.
- Most significant challenge was disentangling formulation from other specific and non-specific processes. Potentially an overlap between concepts of formulation, working alliance and CBT.
- A strong attempt at contributing to sparse literature and studying formulation using scientific methodology within clinical practice.

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